# Innovating Antibodies, Improving Lives

Investor Presentation June 2018





### **Forward Looking Statement**

This presentation contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. All statements other than statements of historical facts included in this presentation, including, without limitation, those regarding our financial position, business strategy, plans and objectives of management for future operations (including development plans and objectives relating to our products), are forward looking statements. Such forward looking statements involve known and unknown risks, uncertainties and other factors which may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by such forward looking statements. Such forward looking statements are based on numerous assumptions regarding our present and future business strategies and the environment in which we will operate in the future. The important factors that could cause our actual results, performance or achievements to differ materially from those in the forward looking statements include, among others, risks associated with product discovery and development, uncertainties related to the outcome of clinical trials, slower than expected rates of patient recruitment, unforeseen safety issues resulting from the administration of our products in patients, uncertainties related to product manufacturing, the lack of market acceptance of our products, our inability to manage growth, the competitive environment in relation to our business area and markets, our inability to attract and retain suitably qualified personnel, the unenforceability or lack of protection of our patents and proprietary rights, our relationships with affiliated entities, changes and developments in technology which may render our products obsolete, and other factors. Further, certain forward looking statements are based upon assumptions of future events which may not prove to be accurate. The forward looking statements in this document speak only as at the date of this presentation. Genmab does not undertake any obligation to update or revise forward looking statements in this presentation nor to confirm such statements to reflect subsequent events or circumstances after the date made or in relation to actual results, unless required by law.



## Genmab At-A-Glance Core Purpose, Strategy & Vision

### Core Purpose

 To improve the lives of patients by creating & developing innovative antibody products



### Our Strategy

- Turn science into medicine
- Build a profitable & successful biotech
- Focus on Core Competence

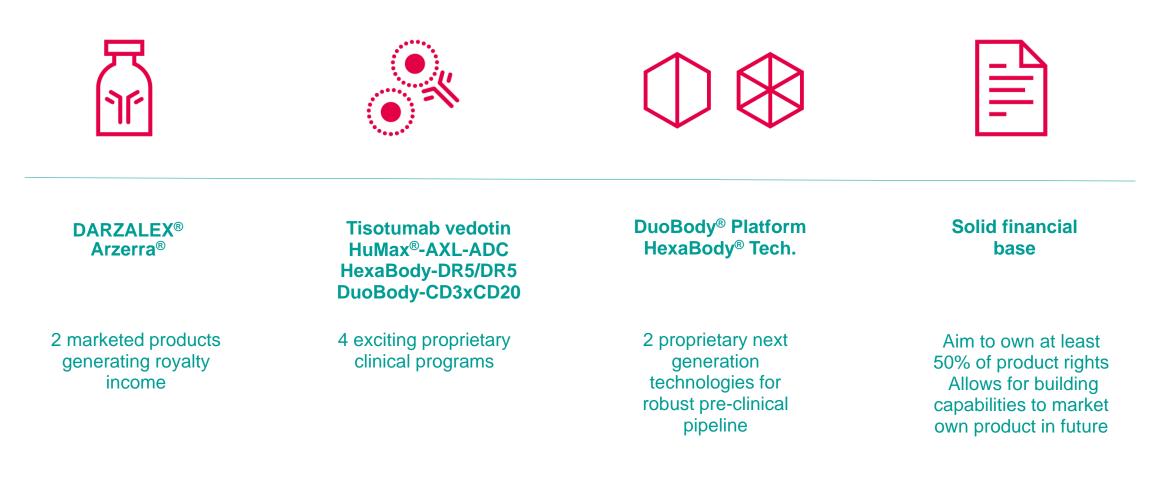


### Vision

 By 2025, our own product has transformed cancer treatment and we have a pipeline of knock-your-socks off antibodies



### **Genmab At-A-Glance** Solid Foundation





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## **Innovative Clinical & Pre-clinical Pipeline**

### **Development for Marketed & Genmab Proprietary Products**

| Product   | Disease Indications                          | Development  | Phase |      |   |  |
|---|--|--------------|-------|------|---|--|
|   |  | Pre-Clinical | Ι     | 1/11 | П |  |
| Daratumumab BTD (2 - MM)  | Multiple myeloma (MM)                        |              |       |      |   |  |
| Target: CD38<br>Partner: Janssen                                    | Amyloidosis                                  |              |       |      |   |  |
|   | Non-MM blood cancers                         |              |       |      |   |  |
| OfatumumabBTD (CLL)(OMB157)Target: CD20Partner: Novartis            | Relapsing multiple sclerosis<br>(RMS) (SubQ) |              |       |      |   |  |
| <b>Tisotumab vedotin</b><br>Target: TF<br>Partner: Seattle Genetics | Solid tumors                                 |              |       |      |   |  |
| HuMax-AXL-ADC<br>Target: AXL  | Solid tumors                                 |              |       |      |   |  |
| HexaBody-DR5/DR5<br>Target: DR5                                     | Solid tumors                                 |              |       |      |   |  |
| DuoBody-CD3xCD20*<br>Targets:CD3, CD20                              | Hematological malignancies                   |              |       |      |   |  |
| *Announced  |  |              |       |      |   |  |



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### Innovative Clinical & Pre-clinical Pipeline Additional Shots on Goal

| Product  | Disease Indications  | Developme    | ent Phase |      |   |   |
|--|--|--------------|-----------|------|---|---|
|  |  | Pre-Clinical | Ι         | 1/11 | П | Ш |
| Teprotumumab (RV001)BTDTarget: IGF-1R, Partner: Horizon Pharma | Graves' orbitopathy  |              |           |      |   |   |
| HuMax-IL8<br>Target: IL8, Partner: BMS                         | Advanced cancers   |              |           |      |   |   |
| ADCT-301 (HuMax-TAC-ADC)                                       | Lymphoma   |              |           |      |   |   |
| Target: CD25, Partner: ADCT                                    | Acute myeloid leukemia (AML) or acute<br>lymphoblastic leukemia (ALL)          |              |           |      |   |   |
| <b>JNJ-61186372</b><br>Targets: EGFR, cMet, Partner: Janssen   | Non-small-cell lung cancer (NSCLC)   |              |           |      |   |   |
| JNJ-63709178<br>Targets: CD3, CD123, Partner: Janssen          | Acute Myeloid Leukemia (AML)   |              |           |      |   |   |
| JNJ-64007957<br>Targets: BCMA, CD3, Partner: Janssen           | Relapsed or refractory MM  |              |           |      |   |   |
| JNJ-64407564<br>Targets: CD3, GPRC5D, Partner: Janssen         | Relapsed or refractory MM  |              |           |      |   |   |
| ~20 Active Pre-clinical programs incl.<br>DuoBody CD40x4-1BB   | Proprietary programs: HuMab, HuMab-<br>ADC, DuoBody, DuoBody-ADC &<br>HexaBody |              |           |      |   |   |
| Aim 4 INDs in 4 Years  | Partnered programs: HuMab, DuoBody & HexaBody                                  |              |           |      |   |   |
|  |  |              |           |      |   |   |

# **Cutting Edge Capabilities**



### Additional Value Created by Technologies

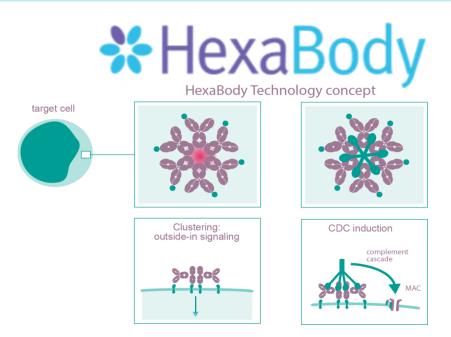


#### **DuoBody Platform**

- Efficient & versatile bispecific Ab platform
- Applicable to any antibody from any platform
- Regular IgG format
- Large scale production validated
- No developability liabilities
- Robotized bispecific library generation
- Multiple ongoing collab. incl. with Novo Nordisk, Gilead & Janssen

#### HexaBody Technology

- Robust effector function enhanced Ab
- Enables antibodies to readily form clusters of 6 (hexamers)
- Induces & enhances target cell killing after binding (CDC and apoptosis)
- Creates innovative products in cancer & infectious diseases
- Multiple ongoing research collaborations





### Daratumumab (Marketed as DARZALEX®) Approved in US, EU & Japan

First-in-class antibody targeting CD38 – 2 FDA BTDs

Marketed as monotherapy in US & EU for double refractory MM

Approved in US, EU & Japan in combo. w/ Revlimid<sup>®</sup> & dex or Velcade<sup>®</sup> & dex for relapsed / refractory MM

Approved in the US in combo. w/ Velcade<sup>®</sup>, melphalan & prednisone for newly diagnosed MM pts ineligible for ASCT & in combo. w/ Pomalyst<sup>®</sup> & dex for pts w/ MM who have received at least 2 prior therapies

Industry sponsored clinical studies ongoing in MM, NKT-cell lymphoma, MDS, and amyloidosis

Blockbuster status – growing royalty income Royalty rate: 12% - 20%

Collaboration w/ Janssen Biotech Up to \$1bn total in dev., reg. & sales milestones, Janssen responsible for all costs assoc. w/ dev. & commercialization See local country prescribing information for precise indications





# **Covering All Stages of MM: Key Ongoing Trials**

| Disease Stage                 | Therapy                   |            | Development Phase         |               |                   |                            |         |  |
|-------------------------------|---------------------------|------------|---------------------------|---------------|-------------------|----------------------------|---------|--|
|                               |                           | No.<br>Pts | Pre-Clinical              | I             | 1/11              | П                          | Ш       |  |
| High Risk Smoldering          | Subcutaneous              | 360        | AQUILA                    |               |                   |                            |         |  |
|                               | Monotherapy               | 126        | CENTAL                    | JRUS          |                   |                            |         |  |
| Front line (transplant & non- | Dara + VMP                | 706        |                           | NE            |                   |                            |         |  |
| transplant)                   | Dara + VMP (Asia Pacific) | 210        |                           |               |                   |                            |         |  |
|                               | Dara + Rd                 | 744        |                           |               |                   |                            |         |  |
|                               | Dara + VTd                | 1,080      | CASSIO                    | PEIA          |                   |                            |         |  |
|                               | Dara + RVd                | 216        | GRIFFIN                   |               |                   |                            |         |  |
| Relapsed or Refractory        | Dara + Vd (China)         | 210        |                           |               |                   |                            |         |  |
|                               | Dara + Kd                 | 450        | CANDO                     | R             |                   |                            |         |  |
|                               | Dara + Pom + d            | 302        | APOLLO                    | D             |                   |                            |         |  |
|                               | Subcutaneous vs IV        | 480        | COLUM                     | BA            |                   |                            |         |  |
|                               | Dara + combinations       | >470       | NINLARO <sup>®</sup> (Pl  | n II), Vencle | exta™ (Ph II),    | Selinexor (P               | h I/II) |  |
|                               | Dara + I.O. (PD1 & PDL1)  | >1,100     | Keytruda <sup>®</sup> (Ph | II), Opdivo   | o® (Ph I/II), Teo | centriq <sup>®</sup> (Ph I | )       |  |
|                               |                           |            |                           |               |                   |                            |         |  |

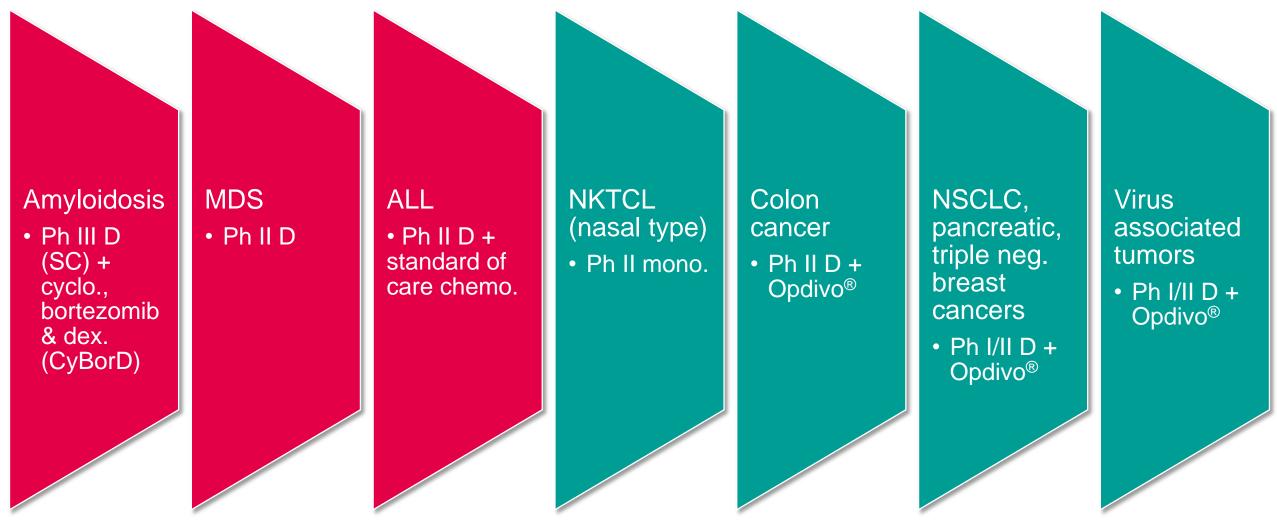
V = Velcade<sup>®</sup>, MP = melphalan-prednisone, T = thalidomide d= dexamethasone, R = Revlilmid<sup>®</sup>, K = Kyprolis<sup>®</sup>, Pom = Pomalyst<sup>®</sup>

Maintenance integrated into some study protocols



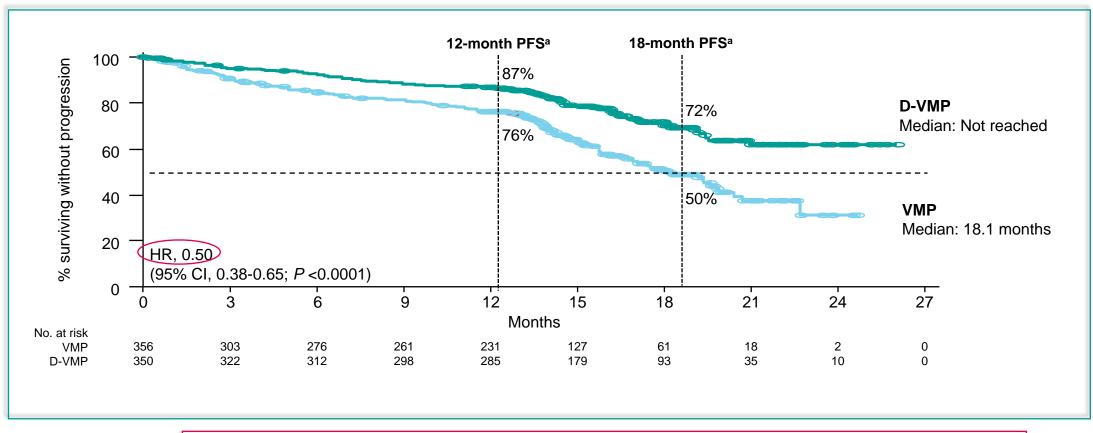
### **Daratumumab Development**

### **Beyond Multiple Myeloma**





### Front Line Multiple Myeloma: ALCYONE Ph III Newly Diagnosed Multiple Myeloma



#### In D-VMP arm:

• 50% reduction risk of disease progression or death in patients receiving D-VMP

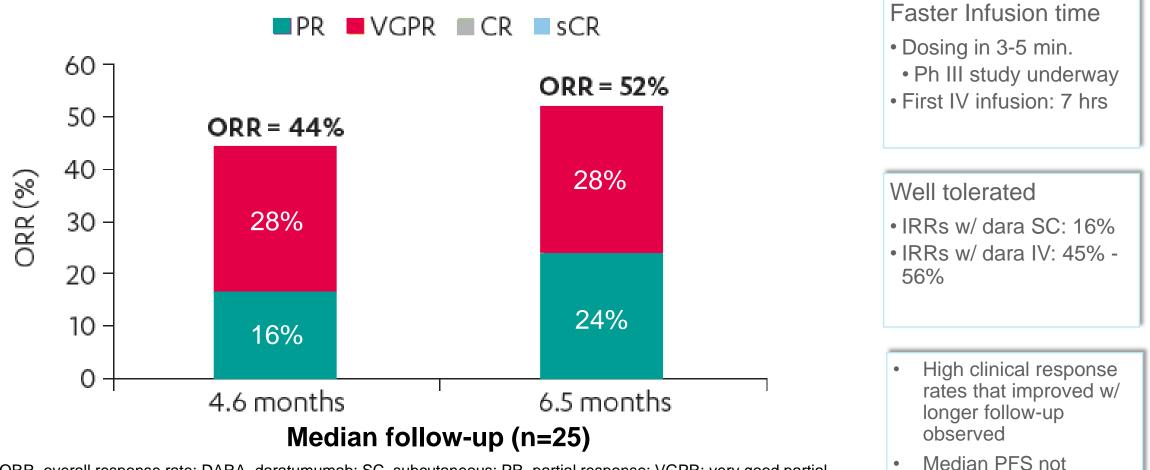
• Median PFS not reached

• >3-fold higher MRD-negative rate

Data Presented at ASH – Atlanta, December 2017 / Basis of FDA Approval (May 2018) & EMA Submission (Nov 2017)<sup>11</sup>

### **Subcutaneous Daratumumab**

PAVO Study in Relapsed or Refractory MM: ORRs in Part 2 (Dara SC 1,800 mg)



ORR, overall response rate; DARA, daratumumab; SC, subcutaneous; PR, partial response; VGPR; very good partial response; CR, complete response; sCR, stringent complete response

#### Presented at ASCO – Chicago, June 2018

reached after median

follow-up of 6.5 mo

Genmab



### **Ofatumumab (Arzerra®)**

Human antibody targeting CD20

Two Phase III studies in relapsing MS ongoing

MS Advantages: Dosing Better disease management, subcutaneous dosing

MS Advantages: Attributes Potential for low immunogenicity, manageable safety profile

Marketed in various territories for certain CLL indications\* In non-US markets, Novartis intends to transition from commercial to compassionate use programs

Collaboration with Novartis Cash flow positive for Genmab





# **Clinical Projects: Tisotumab vedotin**

# Phase II for Cervical Cancer

Fully human antibody-drug conjugate (ADC)

Targets Tissue Factor (TF) Therapeutic potential in broad range of solid tumors

Ph II study in cervical cancer Potential registrational pathway

Ph II study in colorectal, NSCLC, pancreatic, SCCHN

Studies ongoing in solid tumors Indications incl. gynecologic (ovarian, cervical, and endometrial) cancers, prostate, bladder, & esophageal cancers, NSCLC & SCCHN

50:50 Co-development with Seattle Genetics





# **Clinical Projects: HuMax-AXL-ADC**

Efficacy in in vivo Tumor Model

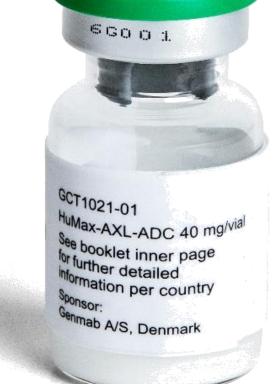
Human ADC

Targets tumor-associated AXL

Therapeutic potential in solid tumors

First-in-human Phase I/II study

- Indications incl. gynecologic (ovarian, cervical, & endometrial) cancers, thyroid cancer, NSCLC and melanoma
- Expansion cohorts initiated in 2018 (NSCLC, melanoma, sarcoma)



ADC technology licensed from Seattle Genetics



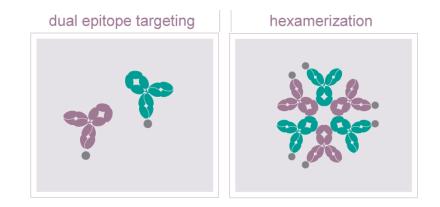
# **Clinical Projects: HexaBody-DR5/DR5** Potential in Solid Tumors

Proprietary HexaBody technology

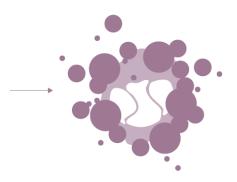
DR5 as tumor target

Phase I/II study initiated in Q2 2018

Potential in solid cancers Colorectal, NSCLC, triple neg. breast cancer, renal cell cancer, gastric cancer, pancreatic cancer & urothelial cancer



Apoptosis by hexamer-induced DR5 clustering and outside-in signaling





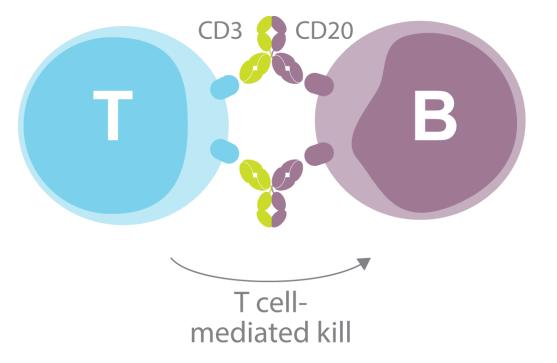
# Clinical Projects: DuoBody-CD3xCD20 Phase I/II Study Planned

Proprietary DuoBody Technology

CD20 & CD3 as therapeutic targets

IND & CTAs filed in Q4 2017 Initiating Phase I/II study in 2018

Potential in B-cell malignancies





# Well-Capitalized Biotech – 2018 Guidance

| Income Statement     | DKKM              | USDM*         |
|----------------------|-------------------|---------------|
| Revenue              | 2,700 – 3,100     | 450 - 517     |
| Operating expenses   | (1,400) – (1,600) | (233) – (267) |
| Operating income     | 1,300 – 1,500     | 217 - 250     |
| *USD 1.00 = DKK 6.00 |                   |               |

2018 Guidance - May 8, 2018

#### **DARZALEX** sales

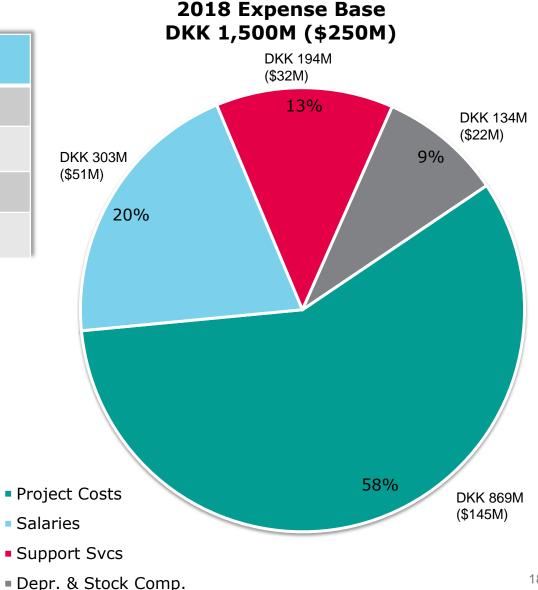
Genmab's estimate of DARZALEX net sales USD 2.0-2.3 billion

#### Revenue mid-point DKK 2,900M

- DARZALEX royalties DKK 1,750M
- **DARZALEX** milestones DKK 550M
- Novartis one-time payment of DKK 300M ٠

#### Expense mid-point DKK 1,500

- Continued investment in our clinical & pre-clinical pipeline
- 10 pipeline projects drive ~DKK 765M, 51% of total expense





### **2018 Company Goals** Maximizing Differentiated Product Portfolio Value

| Priority   | ✓            | Targeted Milestone  |
|--|--------------|---|
| Maximize daratumumab<br>progress   | *            | <ul> <li>» FDA and EMA decision on Phase III ALCYONE multiple myeloma (MM) submission</li> <li>» Start new Phase III MM study</li> <li>» Report early clinical data in solid tumors</li> <li>» Phase III MAIA MM efficacy analysis in frontline</li> <li>» Phase III CASSIOPEIA MM efficacy analysis in frontline</li> </ul>        |
| Optimize of atumumab value   | $\checkmark$ | » Complete recruitment Phase III subcutaneous of atumumab relapsing MS studies  |
| Maximize tisotumab vedotin progress  |              | <ul> <li>» Start two Phase II studies in cervical cancer (recurrent / metastatic &amp; combination study in frontline)</li> <li>» Start Phase II study in additional solid tumor indications</li> </ul>   |
| Strengthen differentiated<br>product pipeline and<br>technology partnership<br>portfolio | ~            | <ul> <li>Start HuMax-AXL-ADC expansion phase in ongoing Phase I/II study</li> <li>Progress HexaBody-DR5/DR5 Phase I/II study</li> <li>Progress DuoBody-CD3xCD20 Phase I/II study</li> <li>Accelerate proprietary DuoBody Immuno-Oncology programs towards clinic</li> <li>Enter new technology or product collaborations</li> </ul> |
| Disciplined financial<br>management and building a<br>commercial footprint               |              | <ul> <li>» Execute controlled company growth with selective investments in product &amp; technology pipeline</li> <li>» Continue investing in building commercialization and launch capabilities</li> </ul>   |



### **Creating Value for Patients & Shareholders**

# Building on 3 central pillars: Focus, Innovation & Execution



2 marketed products



4 proprietary early stage clin. programs



2 proprietary technologies



Robust pre-clinical pipeline

World-class antibody & R&D



Building commercial expertise



Solid financials



Strategic collaborations

expertise



Proven track record

# Innovating Antibodies, Improving Lives



Appendix



### **Publicly Listed Company with Large Free Float**

Large cap, listed on Nasdaq Copenhagen, Denmark & ADR in US

Rest of shares held across world incl. USA UK DK NL

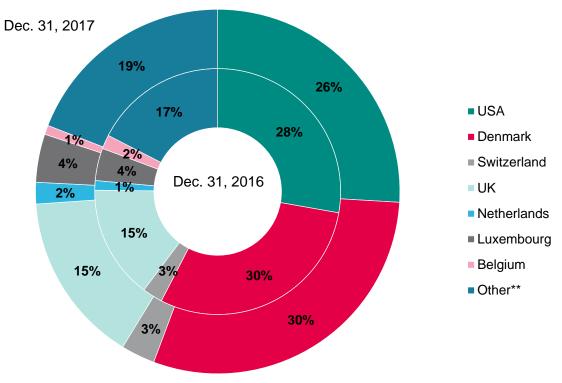
Approx. Market Cap DKK 61 bn USD 9 bn

Approx. shares outstanding: 61.4M

Warrants outstanding: 1.3M (2%)

Approx. diluted shares: 63M

Geographical Shareholder Distribution\* December 31, 2017



\* Based on figures from the internal shareholder register per December 31, 2017

\*\* "Other" includes shares held in other countries and shares not held in nominee accounts, including OTC traded shares

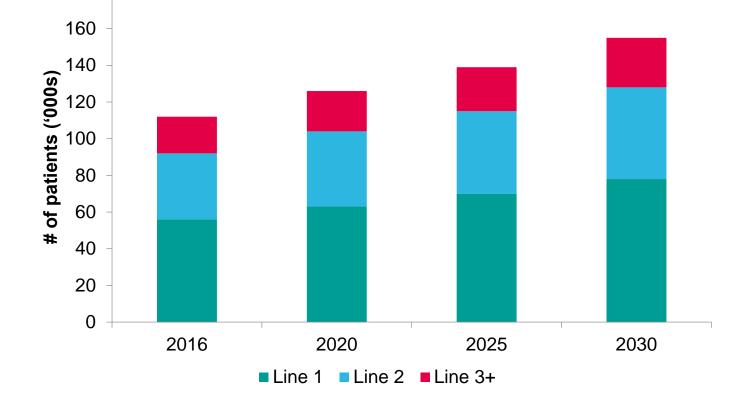


### **Market Opportunity in MM**

- Current projections assume a larger frontline patient population and greater rate of growth over time
- As a disease of the elderly, MM prevalence is expected to rise in line with the growing elderly population
- Incidence is expected to increase in Europe in line with the growing elderly population
- Mortality has significantly decreased due to effectiveness of newer treatments
  - Average lifespan of a patient diagnosed with MM is 7-8 years

#### US and EU5 Drug Treated Patients by Line of Therapy

180





### **DARZALEX®** (daratumumab) Sales Potential



Net sales Full Year 2017

**\$2 - 2.3B** 

Genmab projected 2018 sales

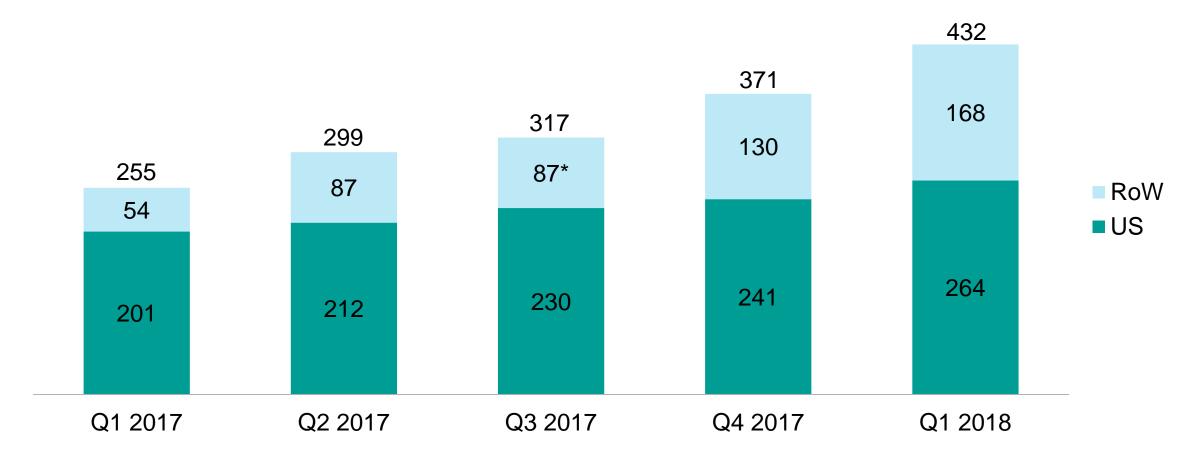


Average analyst\* projected peak MM sales

Potential upside: smoldering disease, other blood cancers, rheumatoid arthritis



# DARZALEX Quarterly Sales Q1 2017 – Q1 2018, USD M

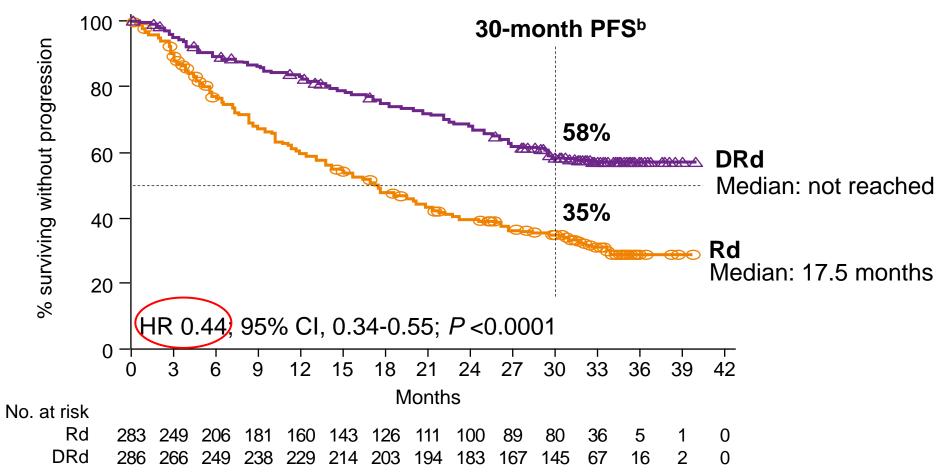


\*RoW sales negatively impacted by one time adjustment of \$20M related to retroactive reimbursement matters in Germany and France.



# **Updated Efficacy: POLLUX**

### Presented ASH 2017



#### 56% reduction in risk of progression/death for DRd versus Rd

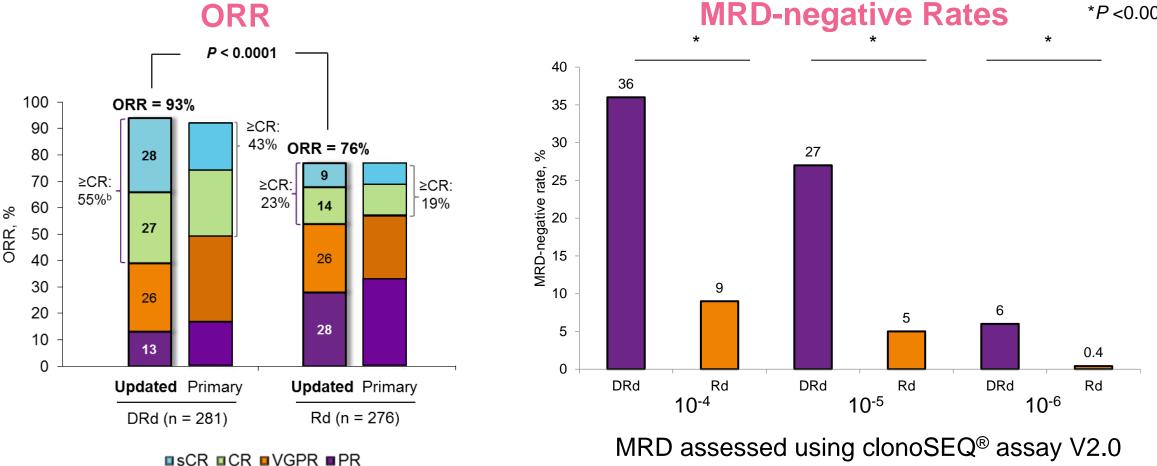
HR, hazard ratio; CI, confidence interval.

<sup>a</sup>Exploratory analyses based on clinical cut-off date of October 23, 2017.

<sup>b</sup>Kaplan-Meier estimate.

### **Updated Efficacy: POLLUX**

### Presented ASH 2017 ORR



Responses continued to deepen in the DRd group

Significantly higher (>3-fold) MRD-negative rates for DRd versus Rd  $\bullet$ 

sCR, stringent complete response; PR, partial response.

Primary analysis reported in Dimopoulos MA, et al. N Engl J Med. 2016;375(14):1319-1331.

<sup>a</sup>Exploratory analyses based on clinical cutoff date of October 23, 2017; <sup>b</sup>P < 0.0001 for DRd versus Rd.

Genmab

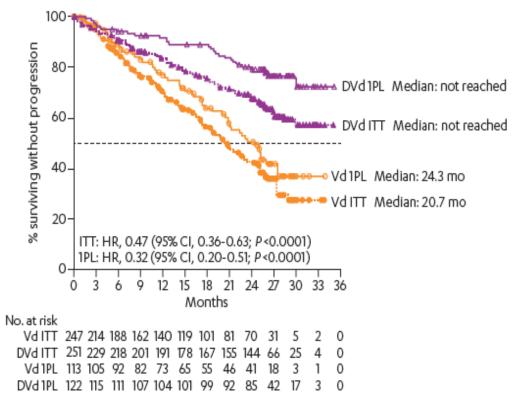
\*P < 0.0001



# **Updated Efficacy: CASTOR**

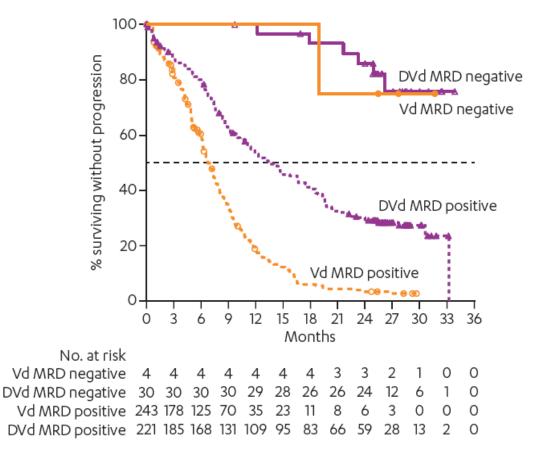
### Presented ASH 2017

**PFS** 



PFS2, progression-free survival on subsequent line of therapy; ITT, intent-to-treat; IPL, 1 prior line of therapy; DVd, daratumumab/bortezomib/ dexamethasone; Vd, bortezomib/dexamethasone.

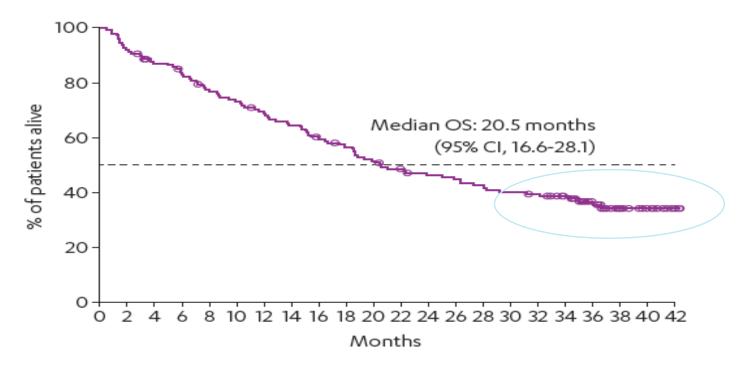
#### **MRD-negative Rates**





### **Updated Efficacy: Monotherapy**



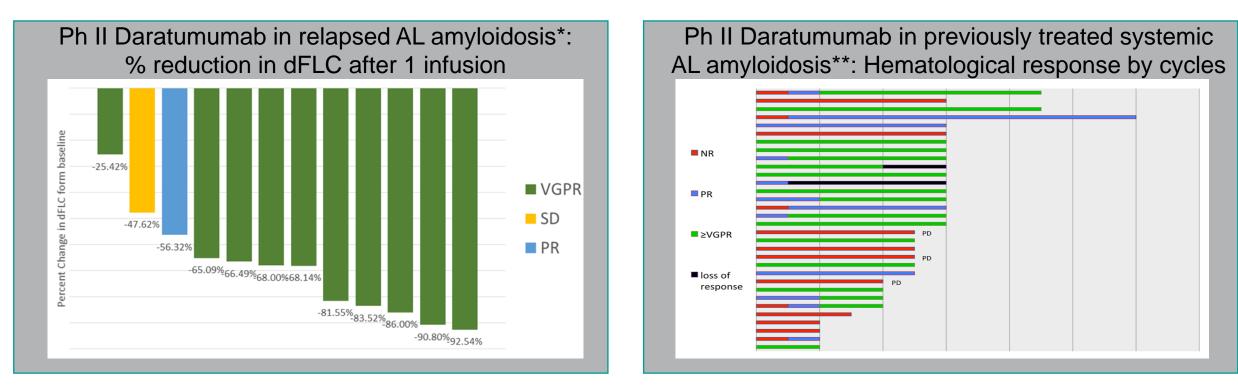


#### Overall survival (OS): combined analysis of GEN501 Part 2 and SIRIUS data.



# Daratumumab in AL Amyloidosis

### Presented at ASH Annual Meeting, Dec. 2017



#### Light chain (AL) amyloidosis

• Occurs when amyloid proteins form deposits that damage tissues and organs

• Most frequently affects kidneys, heart, nervous system, liver & digestive tract

Currently no cure

\*Safety and Tolerability of Daratumumab in Patients with Relapsed Light Chain (AL) Amyloidosis: Preliminary Results of a Phase II Study, Sanchorawala V. et al \*\*A Prospective Phase II of Daratumumab in Previously Treated Systemic Light Chain (AL) Amyloidosis, Roussel M. et al

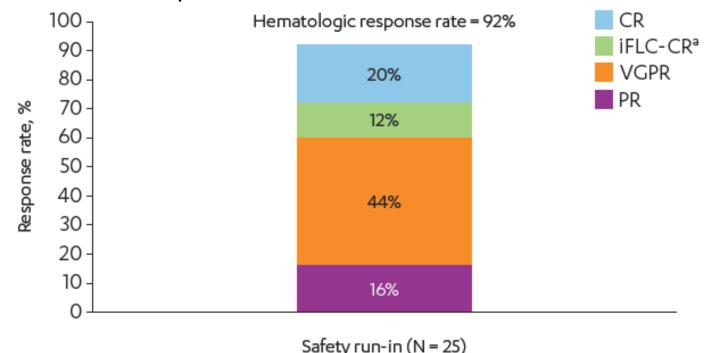
# Daratumumab in AL Amyloidosis con't



Subcutaneous daratumumab plus cyclophosphamide, bortezomib and dexamethasone in patients with newly diagnosed amyloid light chain amyloidosis

Summary of overall best hematologic response based on IACC

Preliminary Efficacy: Except for 2 patients, all remaining patients demonstrated hematologic responses based on IACC Guidelines



IACC, International Amyloidosis Consensus Criteria; CR, complete response; LLN, lower limit of normal; iFLC, involved free light chain; VGPR, very good partial response; PR, partial response. <sup>a</sup>Patients with negative serum and urine immunofixation and normalization of involved FLC level; if uninvolved FLC level is below LLN and FLC ratio is abnormal or normal, patient will be assigned to iFLC-CR (involved FLC CR) response category.

### Presented at ASCO Annual Meeting, June 2018: Safety Run-in Results of ANDROMEDA



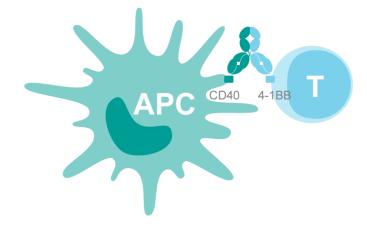
# DuoBody-CD40x4-1BB

### Immunomodulation: targeting two checkpoint activators

#### Bispecific antibody targeting CD40 and 4-1BB (CD137)

- Trans-activating bispecific targeting two checkpoint activators
- Simultaneously activates antigen-presenting cell (APC) and enhances T cell activation
  - Co-engagement of CD40 (APCs) and 4-1BB (T cells) in immune response against tumor
  - Conditional activation and expansion of previously activated cytotoxic CD8<sup>+</sup> T cells
  - Inert Fc backbone
- For treatment of solid cancers
- 2018 IND/CTA candidate
- 50/50 Co-development Genmab and BioNTech







# **Ongoing Daratumumab Clinical Trials**

### Janssen Sponsored Phase II & III

#### Daratumumab Trials Sponsored by Pharma / Biotech

| Ct.gov Identifier | Phase | Sponsor | Indication                                 | Therapy   |
|-------------------|-------|---------|--|---|
| NCT02252172       | III   | Janssen | Untreated MM                               | Daratumumab + Rd (MAIA)                                 |
| NCT02195479       | III   | Janssen | Untreated MM                               | Daratumumab + VMP (ALCYONE)                             |
| NCT02541383       | III   | Janssen | Untreated MM                               | Daratumumab + VTd (CASSIOPEIA)                          |
| NCT02076009       | III   | Janssen | Relapsed or Refractory MM                  | Daratumumab + Rd (POLLUX)                               |
| NCT02136134       | III   | Janssen | Relapsed or Refractory MM                  | Daratumumab + Vd (CASTOR)                               |
| NCT03180736       | III   | Janssen | Relapsed or Refractory MM                  | Daratumumab + Pom-d (APOLLO)                            |
| NCT03201965       | III   | Janssen | Amyloidosis                                | Daratumumab + CyBorD (ANDROMEDA)                        |
| NCT03217812       | III   | Janssen | Untreated MM                               | Daratumumab + VMP (Asia Pacific)                        |
| NCT03234972       | III   | Janssen | Relapsed or Refractory MM                  | Daratumumab + Vd vs Vd (China)                          |
| NCT03277105       | III   | Janssen | Relapsed or Refractory MM                  | Daratumumab SC vs IV (COLUMBA)                          |
| NCT03301220       | III   | Janssen | Smoldering MM                              | Daratumumab SC (AQUILA)                                 |
| NCT03384654       | II    | Janssen | Relapsed / Refractory ALL / LL             | Dara + Vincristine + Prednisone + Doxorubicin (ALL2005) |
| NCT02951819       | П     | Janssen | Untreated and Relapsed MM                  | Daratumumab + CyBorD (LYRA)                             |
| NCT02874742       | II    | Janssen | Untreated MM                               | Daratumumab + RVd (GRIFFIN)                             |
| NCT02316106       | II    | Janssen | Smoldering MM                              | Monotherapy (CENTAURUS)                                 |
| NCT02927925       | II    | Janssen | NKTCL, Nasal Type                          | Monotherapy (NKT2001)                                   |
| NCT03011034       | II    | Janssen | Myelodysplastic Syndromes                  | Daratumumab or Talacotuzumab (MDS2002)                  |
| NCT03412565       | II    | Janssen | Newly diagnosed & relapsed / refractory MM | Daratumumab SC + Rd, VMP & VRd (MMY2040)                |

# Ongoing Daratumumab Clinical Trials Janssen Sponsored Phase I & I/II

#### Daratumumab Trials Sponsored by Pharma / Biotech

| Ct.gov Identifier | Phase | Sponsor | Indication                 | Therapy  |
|-------------------|-------|---------|----------------------------|--|
| NCT01615029       | 1/11  | Janssen | Relapsed and Refractory MM | Daratumumab + Rd (GEN503)  |
| NCT02852837       | I     | Janssen | Relapsed or Refractory MM  | Monotherapy (in China) (MMY1003)   |
| NCT02519452       | I     | Janssen | Relapsed or Refractory MM  | Monotherapy, subcutaneous (PAVO)   |
| NCT02497378       | I     | Janssen | Relapsed or Refractory MM  | Daratumumab + Vd (in Japan) (MMY1005)  |
| NCT02918331       | I     | Janssen | Untreated MM               | Daratumumab + Rd (Japan) (MMY1006)   |
| NCT03242889       | I     | Janssen | Relapsed or Refractory MM  | Daratumumab subq (Japan) (MMY1008)   |
| NCT01998971       | I     | Janssen | Various MM                 | Daratumumab + backbone regimens (Vd, VMP, VTd, Pom-d, Kd, KRd)<br>(EQUULEUS) |
| NCT03320707       | 1     | Janssen | Healthy volunteers         | Daratumumab vs placebo (EDI1001)   |





# **Ongoing Daratumumab Clinical Trials**

### **Other Industry Sponsored Trials**

#### Daratumumab Trials Sponsored by Pharma / Biotech

| Ct.gov Identifier | Phase | Sponsor         |
|-------------------|-------|-----------------|
| NCT03158688       | III   | Amgen           |
| NCT01946477       | II    | Celgene         |
| NCT02807454       | II    | Celgene         |
| NCT02060188       | П     | BMS             |
| NCT03221634       | II    | Merck           |
| NCT03314181       | II    | AbbVie          |
| NCT02807558       | II    | Syros           |
| NCT03439293       | II    | Takeda          |
| NCT02488759       | 1/11  | BMS             |
| NCT03098550       | 1/11  | BMS             |
| NCT02343042       | 1/11  | Karyopharm      |
| NCT03481556       | 1/11  | Oncopeptides AB |
| NCT01592370       | 1/11  | BMS             |
| NCT02431208       | I     | Roche           |
| NCT03068351       | I     | Roche           |

| Indication                          |
|-------------------------------------|
| Relapsed or Refractory MM           |
| Relapsed or Refractory MM           |
| Relapsed and Refractory MM          |
| Recurrent & Metastatic Colon Cancer |
| Relapsed or Refractory MM           |
| Relapsed or Refractory MM           |
| AML & MDS                           |
| Relapsed or Refractory MM           |
| Virus assoc tumors                  |
| Various solid tumors                |
| Relapsed or Refractory MM           |
| Relapsed or Refractory MM           |
| Relapsed or Refractory MM           |
| Resistant or Refractory MM          |
| Resistant or Refractory MM          |

| Therapy                                    |
|--|
| Daratumumab + Kd (CANDOR)                  |
| Daratumumab + Pom-d                        |
| Daratumumab + Imfinzi (FUSION)             |
| Daratumumab + nivolumab                    |
| Daratumumab + Keytruda                     |
| Daratumumab + Venetoclax + dex w/wout bort |
| Daratumumab + SY-1425                      |
| Daratumumab + NINLARO (ixazomib) + Dex     |
| Daratumumab + nivolumab                    |
| Daratumumab + nivolumab                    |
| Daratumumab + Selinexor + Dex              |
| Daratumumab + Melflufen + Dex              |
| Daratumumab + nivolumab                    |
| Daratumumab + Tecentriq (atezolizumab)     |
| Daratumumab + RO6870810                    |



# **Ongoing Daratumumab Clinical Trials** Investigator Sponsored Study (ISS): MM

#### Investigator Sponsored Studies (ISS) of Daratumumab

| Ct.gov Identifier | Phase | Sponsor | Indication                       | Therapy   |
|-------------------|-------|---------|----------------------------------|---|
| NCT02944565       | II    | ISS     | MM                               | Daratumumab accelerated infusion                        |
| NCT02977494       | II    | ISS     | R/R MM & Severe Renal Impairment | Daratumumab + Vd  |
| NCT02626481       | II    | ISS     | Resistant or Refractory MM       | Daratumumab + dexamethasone                             |
| NCT03004287       | II    | ISS     | Newly diagnosed MM               | KTD-Dara-PACE / Dara-KD / Dara-RD                       |
| NCT03012880       | II    | ISS     | Newly diagnosed MM               | Daratumumab+ Ixazomib, Len & Dex                        |
| NCT03143036       | II    | ISS     | RRMM                             | Daratumumab + thalidomide + Dex                         |
| NCT03184194       | II    | ISS     | RRMM                             | Daratumumab + nivolumab w/ or w/out Len & Dex           |
| NCT03188172       | II    | ISS     | Newly diagnosed MM               | Daratumumab + VRd                                       |
| NCT03215524       | II    | ISS     | RRMM                             | Daratumumab + Dex, Cy, Pom                              |
| NCT03224507       | II    | ISS     | Deep remission in MM             | Daratumumab + KRd                                       |
| NCT03290950       | II    | ISS     | Newly Diagnosed MM               | Daratumumab + KRd                                       |
| NCT03289299       | II    | ISS     | Smoldering MM                    | Daratumumab + carfilzomib, lenalidomide & dexamethasone |
| NCT03346135       | II    | ISS     | MM                               | Dara as maintenance after ASCT                          |
| NCT03450057       | П     | ISS     | RRMM w/ renal impairment         | Daratumumab   |
| NCT03475628       | II    | ISS     | Effects on bone disease in RRMM  | Daratumumab   |
| NCT03477539       | П     | ISS     | MM                               | Daratumumab, ASCT, lenalidomide                         |
| NCT03490344       | II    | ISS     | MM                               | Daratumumab, lenalidomide short course                  |
| NCT03500445       | II    | ISS     | Newly diagnosed MM               | Daratumumab, carfilzomib, lenalidomide, low dose Dex    |
| NCT03236428       | I     | ISS     | Smoldering MM                    | Daratumumab   |
| NCT02955810       | I     | ISS     | Untreated MM                     | Daratumumab + CyBorD                                    |
| NCT03311828       | I     | ISS     | Relapsed MM                      | Daratumumab + positron emission tomography              |
| NCT02751255       | 1/11  | ISS     | RRMM                             | Daratumumab + All-trans retinoic acid                   |
| NCT01665794       | 1/11  | ISS     | RRMM                             | Daratumumab + K, Pom, dex                               |



# **Ongoing Daratumumab Clinical Trials** ISS: Other Indications

#### Investigator Sponsored Studies (ISS) of Daratumumab

| Ct.gov Identifier | Phase | Sponsor | Indication  | Therapy                                 |
|-------------------|-------|---------|---|---|
| NCT02816476       | II    | ISS     | Amyloidosis   | Monotherapy                             |
| NCT03067571       | II    | ISS     | AML or MDS  | Monotherapy                             |
| NCT03095118       | II    | ISS     | Membranoproliferative Glomerulonephritis                                    | Monotherapy                             |
| NCT03187262       | II    | ISS     | Waldenstrom macroglobulinemia   | Monotherapy                             |
| NCT03207542       | II    | ISS     | ALL   | Monotherapy                             |
| NCT03473730       | II    | ISS     | Metastatic Renal Cell Carcinoma (MRCC)<br>or Muscle Invasive Bladder Cancer | Monotherapy                             |
| NCT02841033       | 1/11  | ISS     | Amyloidosis   | Monotherapy                             |
| NCT03537599       | 1/11  | ISS     | AML   | Daratumumab + donor lymphocyte infusion |
| NCT03177460       | I     | ISS     | High-risk localized prostate cancer   | Monotherapy with prostatectomy          |
| NCT03432741       | I     | ISS     | RR NHL, Hodgkin lymphoma or Stage IV breast cancer                          | Intralesional injection                 |
| NCT03283917       | I     | ISS     | Amyloidosis   | Daratumumab, ixazomib & dex             |
| NCT03447808       | I     | ISS     | CLL   | Daratumumab & ibrutinib                 |

Pom-d = Pomalyst (pomalidomide) + dexamethasone CyBorD = Cyclophosphamide, bortezomib, dexamethasone KRd = Kyprolis (carfilzomib) + Revlimid (lenalidomide) + dexamethasone VTd = Velcade (bortezomib) + thalidomidde + dexamethasone Vd = Velcade (bortezomib) + dexamethasone VMP = Velcade (bortezomib) + melphalan-prednisone Kd = Kyprolis (carfilzomib) + dexamethasone

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