UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 6-K

REPORT OF FOREIGN PRIVATE ISSUER PURSUANT TO RULE 13a-16 OR 15d-16
OF THE SECURITIES EXCHANGE ACT OF 1934

FOR THE MONTH OF JANUARY 2021

COMMISSION FILE NUMBER 001-38976

Genmab A/S

(Exact name of Registrant as specified in its charter)

Kalvebod Brygge 43
1560 Copenhagen V
Denmark
+45 70 20 27 28
(Address of principal executive offices)

Indicate by check mark whether the registrant files or will file annual reports under cover Form 20-F or Form 40-F.

Form 20-F ☒ Form 40-F ☐

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(1)

Yes ☐ No ☒

Indicate by check mark if the registrant is submitting the Form 6-K in paper as permitted by Regulation S-T Rule 101(b)(7)

Yes ☐ No ☒

This report on Form 6-K shall be deemed to be incorporated by reference in Genmab A/S's registration statements on Form S-8 (File No. 333-232693) and to be a part thereof from the date on which this report is filed, to the extent not superseded by documents or reports subsequently filed or furnished.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

GENMAB A/S

BY: /s/ Anthony Pagano
Name: Anthony Pagano
Title: Executive Vice President & Chief Financial Officer

DATE: January 15, 2021

EXHIBIT INDEX

Exhibit	Description of Exhibit
99.1	Company Announcement Dated January 15, 2021: Genmab Announces that Janssen has been Granted U.S. FDA Approval for DARZALEX FASPRO® (daratumumab and hyaluronidase-fihj) for Patients with Newly Diagnosed Light-chain (AL) Amyloidosis

Genmab Announces that Janssen has been Granted U.S. FDA Approval for DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) for Patients with Newly Diagnosed Light-chain (AL) Amyloidosis

Company Announcement

- **DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj) approved by U.S. FDA as the first and only therapy for newly diagnosed Light-chain (AL) amyloidosis**
- **Accelerated approval of DARZALEX *FASPRO*-based combination regimen supported by the Phase 3 ANDROMEDA (AMY3001) study**
- **Genmab to receive USD 30 million milestone payment on first commercial sale**

Copenhagen, Denmark; January 15, 2021 – Genmab A/S (Nasdaq: GMAB) announced today that the U.S. Food and Drug Administration (U.S. FDA) has approved the use of DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, in combination with bortezomib, cyclophosphamide, and dexamethasone (VCd) for the treatment of adult patients with newly diagnosed light-chain (AL) amyloidosis. A supplemental Biologics License Application (sBLA) for this indication was submitted by Janssen Biotech, Inc. (Janssen), in September 2020. The U.S. FDA reviewed the submission of data for approval in this indication under their Real-Time Oncology Review (RTOR)[1] pilot program and Project Orbis[2]. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). DARZALEX *FASPRO* is not indicated and is not recommended for the treatment of patients with light-chain (AL) amyloidosis who have NYHA Class IIIB or Class IV cardiac disease or Mayo Stage IIIB outside of controlled clinical trials. In August 2012, Genmab granted Janssen an exclusive worldwide license to develop, manufacture and commercialize daratumumab.

“AL amyloidosis is a devastating and potentially fatal blood disorder that, until now, did not have any U.S. FDA-approved therapies. This makes today’s approval of DARZALEX *FASPRO* a critical step forward for patients in the U.S. in dire need of treatment options,” said Jan van de Winkel, Ph.D., Chief Executive Officer of Genmab.

The approval was based on data from the Phase 3 ANDROMEDA (AMY3001) study of daratumumab and hyaluronidase-fihj in combination with VCd as treatment for patients with newly diagnosed AL amyloidosis.

The most common adverse reactions (≥20%) were upper respiratory tract infection, diarrhea, peripheral edema, constipation, fatigue, peripheral sensory neuropathy, nausea, insomnia, dyspnea and cough. Serious adverse reactions occurred in 43% of patients who received DARZALEX *FASPRO* in combination with VCd. Serious adverse reactions that occurred in at least 5% of patients in the D-VCd arm were pneumonia (9%), cardiac failure (8%) and sepsis (5%). Fatal adverse reactions occurred in 11% of patients. Fatal adverse reactions that occurred in more than one patient included cardiac arrest (4%), sudden death (3%), cardiac failure (3%) and sepsis (1%).[3]

Among patients who received DARZALEX *FASPRO* in combination with VCd, 72% of patients had baseline cardiac involvement with Mayo Cardiac Stage I (3%), Stage II (46%) and Stage III (51%). Serious cardiac disorders occurred in 16% of patients (8% of patients with Mayo Cardiac Stage I and II and 28% of patients with Stage III). Serious cardiac disorders in more than 2% of patients included cardiac failure (8%), cardiac arrest (4%) and arrhythmia (4%). Fatal cardiac disorders occurred in 10% of patients (5% of patients with Mayo Cardiac Stage I and II and 19% of patients with Stage III) who received DARZALEX *FASPRO* in combination with VCd. Fatal cardiac disorders that occurred in more than one patient in the D-VCd arm included cardiac arrest (4%), sudden death (3%) and cardiac failure (3%).[3]

Full prescribing information will be available at www.DARZALEX.com.

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Genmab will receive a milestone payment of USD 30 million in connection with the first commercial sale of DARZALEX *FASPRO* in this indication, which is expected to occur quickly after approval. The milestone will be reflected in Genmab's 2021 guidance, which will be published on February 23, 2021.

About the ANDROMEDA (AMY3001) study
The Phase 3 study (NCT03201965) included 388 patients newly diagnosed with AL amyloidosis. Patients were randomized to receive treatment with either daratumumab and hyaluronidase-fihj in combination with bortezomib (a proteasome inhibitor), cyclophosphamide (a chemotherapy), and dexamethasone (a corticosteroid) or treatment with VCd alone. The primary endpoint of the study was the percentage of patients who achieve hematologic complete response.

About Light-chain (AL) Amyloidosis
Amyloidosis is a disease that occurs when amyloid proteins, which are abnormal proteins, accumulate in tissues and organs. When the amyloid proteins cluster together, they form deposits that damage the tissues and organs. AL amyloidosis most frequently affects the heart, kidneys, liver, nervous system and digestive tract. Until now there were no approved therapies for AL amyloidosis in the U.S., though it is currently being treated with chemotherapy, dexamethasone, stem cell transplants and supportive therapies.[4] It is estimated that there are approximately 3,000 to 4,000 new cases of AL amyloidosis diagnosed annually in the U.S.[5]

About DARZALEX® (daratumumab)
DARZALEX® (daratumumab) has become a backbone therapy in the treatment of multiple myeloma. DARZALEX intravenous infusion is indicated for the treatment of adult patients in the United States: in combination with carfilzomib and dexamethasone for the treatment of patients with relapsed/refractory multiple myeloma who have received one to three previous lines of therapy; in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of patients with multiple myeloma who have received at least one prior therapy; in combination with pomalidomide and dexamethasone for the treatment of patients with multiple myeloma who have received at least two prior therapies, including lenalidomide and a proteasome inhibitor (PI); and as a monotherapy for the treatment of patients with multiple myeloma who have received at least three prior lines of therapy, including a PI and an immunomodulatory agent, or who are double-refractory to a PI and an immunomodulatory agent.[6] DARZALEX is the first monoclonal antibody (mAb) to receive U.S. Food and Drug Administration (U.S. FDA) approval to treat multiple myeloma.

DARZALEX is indicated for the treatment of adult patients in Europe via intravenous infusion or subcutaneous administration: in combination with bortezomib, thalidomide and dexamethasone as treatment for patients newly diagnosed with multiple myeloma who are eligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of adult patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; for use in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone, for the treatment of adult patients with multiple myeloma who have received at least one prior therapy; and as monotherapy for the treatment of adult patients with relapsed and refractory multiple myeloma, whose prior therapy included a PI and an immunomodulatory agent and who have demonstrated disease progression on the last therapy[7]. Daratumumab is the first subcutaneous CD38 antibody approved in Europe for the treatment of multiple myeloma. The option to split the first infusion of DARZALEX over two consecutive days has been approved in both Europe and the U.S.

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In Japan, DARZALEX intravenous infusion is approved for the treatment of adult patients: in combination with lenalidomide and dexamethasone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with bortezomib, melphalan and prednisone for the treatment of patients with newly diagnosed multiple myeloma who are ineligible for autologous stem cell transplant; in combination with lenalidomide and dexamethasone, or bortezomib and dexamethasone for the treatment of relapsed or refractory multiple myeloma. DARZALEX is the first human CD38 monoclonal antibody to reach the market in the United States, Europe and Japan. For more information, visit www.DARZALEX.com.

DARZALEX *FASPRO*® (daratumumab and hyaluronidase-fihj), a subcutaneous formulation of daratumumab, is approved in the United States for the treatment of adult patients with newly diagnosed light-chain (AL) amyloidosis in combination with bortezomib, cyclophosphamide, and dexamethasone. It is also approved in the U.S. for the treatment of adult patients with multiple myeloma: in combination with bortezomib, thalidomide, and dexamethasone in newly diagnosed patients who are eligible for ASCT; in combination with bortezomib, melphalan and prednisone in newly diagnosed patients who are ineligible for ASCT; in combination with lenalidomide and dexamethasone in newly diagnosed patients who are ineligible for ASCT and in patients with relapsed or refractory multiple myeloma who have received at least one prior therapy; in combination with bortezomib and dexamethasone in patients who have received at least one prior therapy; and as monotherapy, in patients who have received at least three prior lines of therapy including a PI and an immunomodulatory agent or who are double-refractory to a PI and an immunomodulatory agent.[8] DARZALEX *FASPRO* is co-formulated with recombinant human hyaluronidase PH20 (rHuPH20), Halozyme's ENHANZE® drug delivery technology. DARZALEX *FASPRO* is the first subcutaneous CD38 antibody approved in the U.S. for the treatment of multiple myeloma and the first and only approved treatment for patients with AL amyloidosis in the U.S.

Daratumumab is a human IgG1k monoclonal antibody (mAb) that binds with high affinity to the CD38 molecule, which is highly expressed on the surface of multiple myeloma cells. Daratumumab triggers a person's own immune system to attack the cancer cells, resulting in rapid tumor cell death through multiple immune-mediated mechanisms of action and through immunomodulatory effects, in addition to direct tumor cell death, via apoptosis (programmed cell death).[6,9,10,11,12]

Daratumumab is being developed by Janssen Biotech, Inc. under an exclusive worldwide license to develop, manufacture and commercialize daratumumab from Genmab. A comprehensive clinical development program for daratumumab is ongoing, including multiple Phase III studies in smoldering, relapsed and refractory and frontline multiple myeloma settings. Additional studies are ongoing or planned to assess the potential of daratumumab in other malignant and pre-malignant diseases in which CD38 is expressed, such as amyloidosis and T-cell acute lymphocytic leukemia (ALL). Daratumumab has received two Breakthrough Therapy Designations from the U.S. FDA for certain indications of multiple myeloma, including as a monotherapy for heavily pretreated multiple myeloma and in combination with certain other therapies for second-line treatment of multiple myeloma.

About Genmab
Genmab is an international biotechnology company with a core purpose to improve the lives of patients with cancer. Founded in 1999, Genmab is the creator of multiple approved antibody therapeutics that are marketed by its partners. The company aims to create, develop and commercialize differentiated therapies by leveraging next-generation antibody technologies, expertise in antibody biology, translational research and data sciences and strategic partnerships. To create novel therapies, Genmab utilizes its next-generation antibody technologies, which are the result of its collaborative company culture and a deep passion for innovation. Genmab's proprietary pipeline consists of modified antibody candidates, including bispecific T-cell engagers and next-generation immune checkpoint modulators, effector function enhanced antibodies and antibody-drug conjugates. The company is headquartered in Copenhagen, Denmark with locations in Utrecht, the Netherlands, Princeton, New Jersey, U.S. and Tokyo, Japan. For more information, please visit Genmab.com.

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This Company Announcement contains forward looking statements. The words "believe", "expect", "anticipate", "intend" and "plan" and similar expressions identify forward looking statements. Actual results or performance may differ materially from any future results or performance expressed or implied by such statements. The important factors that could cause our actual results or performance to differ materially include, among others, risks associated with pre-clinical and clinical development of products, uncertainties related to the outcome and conduct of clinical trials including unforeseen safety issues, 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 or technologies obsolete, and other factors. For a further discussion of these risks, please refer to the risk management sections in Genmab's most recent financial reports, which are available on www.genmab.com and the risk factors included in Genmab's most recent Annual Report on Form 20-F and other filings with the U.S. Securities and Exchange Commission (SEC), which are available at www.sec.gov. Genmab does not undertake any obligation to update or revise forward looking statements in this Company Announcement 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.

[1] Real-Time Oncology Review Pilot Program. https://www.fda.gov/about-fda/oncology-center-excellence/real-time-oncology-review-pilot-program Accessed September 2020
[2] Project Orbis. U.S. Food and Drug Administration. https://www.fda.gov/about-fda/oncology-center-excellence/project-orbis. Accessed September 2020.
[3]DARZALEX *FASPRO*® Prescribing Information. Horsham, PA: Janssen Biotech, Inc.
[4] Mayo Clinic website: www.mayoclinic.com/health/amyloidosis/DS00431
[5] Research and Markets, "Amyloidosis Treatment Market Size, Share & Trends Analysis Report by Treatment (Stem Cell Transplant, Chemotherapy, Supportive Care, Surgery, Targeted Therapy), By Country, And Segment Forecasts, 2018 - 2025
[6] DARZALEX Prescribing information, August 2020 https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761036s029lbl.pdf Last accessed August 2020
[7] DARZALEX Summary of Product Characteristics, available at https://www.ema.europa.eu/en/medicines/human/EPAR/darzalex Last accessed June 2020
[8] DARZALEX *FASPRO* Prescribing information, May 2020. Available at: https://www.accessdata.fda.gov/drugsatfda_docs/label/2020/761145s000lbl.pdf Last accessed May 2020
[9] De Weers, M et al. Daratumumab, a Novel Therapeutic Human CD38 Monoclonal Antibody, Induces Killing of Multiple Myeloma and Other Hematological Tumors. The Journal of Immunology. 2011; 186: 1840-1848.
[10] Overdijk, MB, et al. Antibody-mediated phagocytosis contributes to the anti-tumor activity of the therapeutic antibody daratumumab in lymphoma and multiple myeloma. MAbs. 2015; 7: 311-21.
[11] Krejcik, MD et al. Daratumumab Depletes CD38+ Immune-regulatory Cells, Promotes T-cell Expansion, and Skews T-cell Repertoire in Multiple Myeloma. Blood. 2016; 128: 384-94.
[12] Jansen, JH et al. Daratumumab, a human CD38 antibody induces apoptosis of myeloma tumor cells via Fc receptor-mediated crosslinking. Blood. 2012; 120(21): abstract 2974