PRESS RELEASE

DEBIOPHARM'S CD37 ANTIBODY DRUG CONJUGATE SHOWS PROMISING PHASE II RESULTS FOR THE TREATMENT OF B-CELL MALIGNANCIES

- *Diffuse large B-cell lymphoma (DLBCL) is the most common aggressive form of Non-Hodgkin's Lymphoma (NHL), representing 30-40% of cases. Nearly half of DLBCL patients are not cured by first-line treatment, leaving a large number of patients at risk of worsening disease*[1]
- *Naratuximab emtansine, the most advanced CD37 targeting antibody drug conjugate (ADC) in clinical development for DLBCL, showed promising safety and efficacy results in combination with rituximab for the treatment of R/R DLBCL and other B-cell malignancies*
- *Phase II data presented by Dr. Moshe Yair Levy at the 2021 European Hematology Association (EHA) conference as a late breaking abstract (LB1903) demonstrated that the naratuximab emtansine/rituximab combination could represent a new treatment approach, particularly for heavily pre-treated relapsed/refractory (R/R) DLBCL patients*

Lausanne, Switzerland – June 14th, 2021 – Debiopharm (www.debiopharm.com), a Swiss-based global biopharmaceutical company, today announced the phase II results assessing naratuximab emtansine (Debio 1562, formerly IMGN529) for the treatment of DLBCL and other B-cell malignancies. This open label, multicenter, adaptive study was designed to evaluate the safety and efficacy of naratuximab emtansine co-administered with rituximab (anti-CD20 antibody) in patients with R/R NHL (N=100), including a large proportion of heavily pretreated patients with advanced DLBCL. Part of Debiopharm's expanding oncology portfolio, this novel ADC specifically targets the CD37 antigen on the surface of B-cells to release a toxic DM1 payload, offering an alternative therapeutic target for the treatment of B-cell malignancies.

NHL ranked as the 5th to 9th most common cancer in most countries worldwide, with over half a million new cases estimated in 2018.[2] Despite substantial improvements in patient outcomes through chemotherapy, radiotherapy, biologic therapy, or stem cell transplant (SCT), some patients still show resistance to 1st and 2nd lines of treatment, or are not eligible for stem cell transplantation, affecting patient survival.[3] The need for improved patient outcomes sparked the need to explore novel therapeutic strategies, such as targeting the CD37 antigen in addition to the standard-of-care approach.

EHA late breaking abstract results presented on June 12th, revealed meaningful efficacy and high complete response rates (CRR), especially in heavily pre-treated patients with ≥2 prior lines of treatment, in combination with rituximab. Objective Response Rate (ORR) in all efficacy-evaluable patients (N=76) was 44.7%, CRR was 31.6%. In patients with ≥2 prior therapies, non-primary refractory (N=28) ORR was 46.4% and CRR was 32.1%. Sustained responses were observed with a median Duration of Response (DoR) not yet reached and 66% of responders having a DoR >12 months. The safety profile was predictable and manageable, with a low rate of treatment discontinuation due to adverse events (8%) and low incidence of serious febrile neutropenia (4%).

"We now see this alternative combination targeting both CD37 and CD20 could address the unmet need of DLBCL patients who have relapsed or not responded to earlier lines of treatment", explained **Bertrand Ducrey, CEO of Debiopharm, "***These promising efficacy results and good safety profile are motivation for further exploration of the potential benefit that this potent ADC technology could bring to patients. We've clearly arrived at the stage of selecting a partner to unfold the full value of this novel therapeutic option."*

"These results are particularly impressive for heavily pre-treated DLBCL patients for whom options are remain limited," stated **Dr. Moshe Yair Levy, Director of hematologic malignancies research at Baylor University Medical Center** *"The high response rates and durability combined with the manageable safety profile offer a strong rationale for further research of naratuximab emtansine in B-cell malignancies."*

About naratuximab emtansine (Debio 1562)

Naratuximab emtansine is a potential new treatment for patients with B-cell malignancies. The ADC binds with high affinity and specificity to CD37, obstructing cell proliferation pathways following internalization, processing, and intracellular release of the DM1 payload, subsequently inducing cell cycle arrest and apoptosis. Benefiting from Orphan Drug status, the compound demonstrated evidence of anti-cancer activity in DLBCL, as well as promising signs of efficacy in Mantle Cell Lymphoma, Follicular Lymphoma, and potential in Acute Myeloid Leukemia.

Debiopharm's commitment to patients

Debiopharm, Swiss Biotech Success Story award winner, develops innovative therapies that target high unmet medical needs in oncology and infectious diseases. Bridging the gap between disruptive discovery products and real-world patient reach, we identify high-potential compounds and technologies for in-licensing, clinically demonstrate their safety and efficacy and then select large pharmaceutical commercialization partners to maximize patient access globally.

For more information, please visit www.debiopharm.com

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1. ***Hicks SW et al. Neoplasia. 2017Sep; 19(9): 661–671.***
2. **Adalberto Miranda-Filho A et al. Cancer Causes Control 2019 May;30(5):489-499.**
3. **Leukemia, Lymphoma, Myeloma Facts 2014-2015. Leukemia and Lymphoma Society. pg 15, 2015.**