Specialised Therapeutics Enters into a New Supply and Distribution Agreement with Incyte to Launch Two New Cancer Therapies

Singapore, 22 October 2021: Independent pharmaceutical company Specialised Therapeutics Asia Pte Ltd (ST) will partner with Incyte Biosciences International Sàrl, the Swiss-based affiliate of Incyte (NASDAQ:INCY), to launch and distribute two new medicines for its haematology and oncology portfolios, tafasitamab (sold as Monjuvi® in the United States and Minjuvi® in Europe) and pemigatinib (Pemazyre®).

Under the terms of the agreement, Incyte will be responsible for the development, manufacture and supply of both products and ST will be responsible for regulatory, distribution and local marketing related activities in Australia, New Zealand and Singapore.

Pemigatinib is approved in the United States, Europe and Japan for the treatment of adult patients with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Tafasitamab in combination with lenalidomide is approved in the United States and Europe for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

ST Chief Executive Officer Mr Carlo Montagner said the new products were synergistic with the company's strong oncology and haematology portfolios, and the new agreement was further endorsement of ST's regional capabilities.

"We are proud to have been selected to partner with a world-leading biotech of Incyte's calibre and look forward to these important products in our key regions," he said.

“Both pemigatinib and tafasitamab address strong unmet needs in rare patient populations. We have extensive experience and a successful track record of working with clinicians and other stakeholders to bring innovative therapies to small patient populations where there is high unmet clinical need. Our teams look forward to working closely with Incyte to ensure all eligible patients have access to these therapies at the earliest opportunity.”

Incyte CEO Hervé Hoppenot said the latest collaboration and partnership provided an important strategic opportunity to further serve the global oncology community, offering innovative new medicines to patients with high unmet needs in Australia, New Zealand and Singapore.

“ST’s expertise in these regions, navigating complex regulatory channels to bring new therapies and technologies to patients with rare cancers, is complementary to our own commitment to positively impact the lives of patients with serious unmet medical needs,” he said. “We look forward to a successful and mutually beneficial partnership, working together with a shared goal of improving patient outcomes.”

Regulatory activities for both products are currently in progress.

Ends.

About Specialised Therapeutics

Headquartered in Singapore, Specialised Therapeutics Asia Pte Ltd (ST) is an international biopharmaceutical company established to commercialise new therapies and technologies to patients throughout South-East Asia, as well as in Australia and New Zealand. ST and its regional affiliates collaborate with leading global pharmaceutical and diagnostic companies to bring novel, innovative and life-changing healthcare solutions to patients affected by a range of diseases. Its mission is to provide therapies where there is an unmet need. The company’s broad therapeutic portfolio currently includes novel agents in oncology, haematology, neurology, ophthalmology and supportive care. Additional information can be found at www.stbiopharma.com

About Tafasitamab

Tafasitamab is a humanized Fc-modified cytolytic CD19 targeting monoclonal antibody. In 2010, MorphoSys licensed exclusive worldwide rights to develop and commercialize tafasitamab from Xencor, Inc. Tafasitamab incorporates an XmAb® engineered Fc domain, which mediates B-cell lysis through apoptosis and immune effector mechanism including antibody-dependent cell-mediated cytotoxicity (ADCC) and antibody-dependent cellular phagocytosis (ADCP).

In January 2020, MorphoSys and Incyte entered into a Collaboration and License agreement to further develop and commercialize tafasitamab globally. Monjuvi® is being co-commercialized by Incyte and MorphoSys in the United States. Incyte has exclusive commercialization rights outside the United States.

In the United States, Monjuvi® (tafasitamab-cxix) is approved by the U.S. Food and Drug Administration in combination with lenalidomide for the treatment of adult patients with relapsed or refractory DLBCL not otherwise specified, including DLBCL arising from low grade lymphoma, and who are not eligible for autologous stem cell transplant (ASCT). This indication is approved under accelerated approval based on overall response rate. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Europe, Minjuvi® (tafasitamab) received conditional approval, in combination with lenalidomide, followed by Minjuvi monotherapy, for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL) who are not eligible for autologous stem cell transplant (ASCT).

Tafasitamab is being clinically investigated as a therapeutic option in B-cell malignancies in several ongoing combination trials.

 Tafasitamab is co-marketed by Incyte and MorphoSys under the brand name Monjuvi® in the U.S., and marketed by Incyte under the brand name Minjuvi® in the EU.

XmAb® is a trademark of Xencor, Inc.

About Pemigatinib

Pemigatinib (Pemazyre®) is a kinase inhibitor indicated in the United States for the treatment of adults with previously treated, unresectable locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or other rearrangement as detected by an FDA-approved test. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s).

In Japan, Pemazyre is approved for the treatment of patients with unresectable biliary tract cancer (BTC) with a fibroblast growth factor receptor 2 (FGFR2) fusion gene, worsening after cancer chemotherapy.

In Europe, Pemazyre is approved for the treatment of adults with locally advanced or metastatic cholangiocarcinoma with a fibroblast growth factor receptor 2 (FGFR2) fusion or rearrangement that have progressed after at least one prior line of systemic therapy.

Pemazyre is a potent, selective, oral inhibitor of FGFR isoforms 1, 2 and 3 that, in preclinical studies, has demonstrated selective pharmacologic activity against cancer cells with FGFR alterations.

Pemazyre is marketed by Incyte in the United States, Europe and Japan. Incyte has established various license or distribution agreements for Pemazyre in certain geographies and retains all other rights to develop and commercialize pemigatinib outside of the United States.

Pemazyre is a trademark of Incyte.

Further Enquiries

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