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Sobi™ completes acquisition of the global rights for emapalumab from Novimmune

Following approvals from relevant competition authorities, Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO: SOBI) has completed the acquisition of the perpetual global rights to emapalumab from Novimmune SA. That Sobi had entered into an exclusive licence agreement for the acquisition of the perpetual global rights to emapalumab was announced on 20 July 2018.

Emapalumab is a late-stage orphan drug candidate for the treatment of primary Haemophagocytic lymphohistiocytosis (HLH), developed by Novimmune SA, a privately-held, pre-commercial drug discovery and development company focused on rare inflammatory diseases, immune disorders and immuno-oncology.

Highlights of the acquisition

- Strategic partnership to develop and commercialise emapalumab, a highly attractive late stage orphan drug candidate that addresses a high unmet medical need in primary Haemophagocytic lymphohistiocytosis (HLH).
- Emapalumab provides an attractive near-term commercial opportunity for Sobi with sales potential from 2019 onwards, and with an estimated annual SEK 2.5-3.0 B peak sales potential.
- Emapalumab application for US regulatory approval was filed with the FDA in March 2018 with a regulatory decision expected towards the end of 2018. Breakthrough Designation has been granted by the FDA. In Europe, emapalumab has been granted eligibility for the PRIME (PRIority MEdicine) scheme by the EMA. Novimmune submitted a Marketing Authorisation Application (MAA) for emapalumab to EMA in August 2018.
- Emapalumab has potential therapeutic value in other serious medical conditions, with studies in secondary HLH and haematopoietic stem cell transplant (HSCT) ongoing or being planned.
- Upfront payment of CHF 50 M (SEK 450 M) in cash, with a total of CHF 400 M (SEK 3,600 M) in additional payments over an eight year period. Upon payment of all additional amounts, the intellectual property related to emapalumab, including patent rights, data and know-how, will be transferred to Sobi. The additional payments may be accelerated by either party any time after 1 July 2019.
- A non-binding letter of intent for a possible subsequent acquisition of all emapalumab assets has been signed.

Forward looking statements

This press release contains forward-looking statements, including statements regarding the potential benefits that may be derived from the licencing agreement regarding emapalumab, plans and expected timing with respect to the potential approval of emapalumab in the US, as well as potential future sales of emapalumab. These forward-looking statements are based on management expectations and assumptions as of the date of this press release, and actual results may differ materially from those in these forward-looking statements as a result of various factors. These factors include risks that the filings with the FDA and EMA are not approved and that adequate pricing and reimbursement for emapalumab in the US and Europe is not available. Forward-looking statements speak only as of the date of this press release and Sobi does not undertake any obligation to update or revise these statements, except as may be required by law or regulation.

About Sobi™

Sobi™ is an international biopharmaceutical company dedicated to rare diseases. Our vision is to be recognised as a global leader in providing access to innovative treatments that transform lives for individuals with rare diseases. The product portfolio is primarily focused on treatments in Haemophilia and Specialty Care. Partnering in the development and commercialisation of products in specialty care is a key element of our strategy. Sobi has pioneered in biotechnology with world-class capabilities in protein biochemistry and biologics manufacturing. In 2017, Sobi had total revenues of SEK 6.5 billion and approximately 850 employees. The share (STO:SOBI) is listed on Nasdaq Stockholm. More information is available at www.sobi.com.

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