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Sobi™ to acquire Synagis® US rights from AstraZeneca - creates a platform for global growth

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Swedish Orphan Biovitrum AB (publ) (Sobi™) (STO:SOBI) has entered into agreements to acquire the perpetual rights to Synagis® (palivizumab) in the US from AstraZeneca and to participate in 50 per cent of the future earnings of the candidate drug MEDI8897 in the US. The total upfront consideration corresponds to USD 1,500 M (SEK 13.6 B[1]), consisting of USD 1,000 M (SEK 9.1 B) in cash and USD 500 M (SEK 4.5 B) equivalent in newly issued Sobi shares. In addition, deferred and contingent payments depending on certain conditions may be payable, in amounts as further set out below.

Highlights:

- **Diversifies Sobi's revenue base in Specialty Care – Immunology;**Synagis, the only approved respiratory syncytial virus (RSV) prophylaxis for high-risk infants, complements Sobi's expertise in paediatrics and immunology. Synagis bolsters the importance of Sobi's Immunology franchise (to consist of Kineret®, emapalumab[2] and Synagis), and Immunology will constitute the majority share of total Specialty Care sales;
- **Accelerates build-up of US commercial platform;** The acquisition of Synagis is expected to more than double both the revenue and size of Sobi's US organisation, enhancing the financial contribution of the US to Sobi's overall revenues to approximately one third. Access to a proven US sales & marketing organisation will establish a critical scale to drive sustainable growth in the US;
- **Enhances financial capacity;** Significant top line addition will give Sobi substantial recurring earnings to further advance the US expansion and enable future strategic acquisitions over the mid-term, positioning the company well for its next phase of growth. Synagis sales for LTM[3] 30 June 2018 was USD 269 M (SEK 2.4 B). Sobi expects the product to generate an EBITA[4] margin in excess of 60 per cent and that the transaction will be accretive to earnings per share in 2019.

Synagis is a medicine for the prevention of serious lower respiratory tract infections (LRTI) caused by RSV in high-risk infants and is the only approved preventative medicine for the condition. Synagis is an attractive product for Sobi due to its orphan-sized paediatric patient population and immunology profile. Sobi will be responsible for the commercialisation of Synagis in the US. MEDI8897 is a follow-on candidate to Synagis and a monoclonal antibody (mAb) being investigated for the prevention of LRTI caused by RSV in a larger patient population.

"I am excited about adding Synagis to our portfolio as it remains the only product preventing RSV infection in this vulnerable patient group with a great medical need. The addition of Synagis will become an important strategic catalyst for Sobi's future development and will form a powerful platform for growth in rare diseases. We see the acquisition as a stepping stone to drive sustainable growth in the US and make Sobi more attractive for partnering. It also increases the overall Specialty Care franchise and diversifies our portfolio in Immunology. The expected earnings of this acquisition will increase the financial flexibility to support further growth initiatives", comments Sobi President and CEO Guido Oelkers.

"Sobi's focus on Synagis will enable infants in the US to continue benefiting from this important treatment. Meanwhile, the successful development and commercialisation of MEDI8897 remains important for AstraZeneca", comments AstraZeneca's CEO, Pascal Soriot.

Terms of the transaction
The upfront consideration payable at closing of the acquisition will be USD 1,500 M (SEK 13.6 B) consisting of cash and newly issued Sobi common shares. Sobi will also pay USD 20 M (SEK 181 M) in cash, per year, for the three years 2019-2021 as consideration for MEDI8897. Sobi may pay up to USD 470 M (SEK 4.3 B) for Synagis sales-related milestones from 2026 onwards, plus, USD 175 M (SEK 1.6 B) following submission of the Biologics License Application (BLA) to the US Food and Drug Administration (FDA) for MEDI8897. The agreement also includes potential net payments of approximately USD 110 M (SEK 1.0 B) on achievement of other MEDI8897 profit and development-related milestones. MEDI8897 associated payments, if payable, are expected from 2023 onwards.

Following completion of the acquisition, AstraZeneca will hold 8.1 per cent of the total shares and votes in Sobi. AstraZeneca has undertaken not to sell the shares received as consideration for a period of 12 months, and not to acquire additional shares in Sobi for a period of 18 months, following the closing date of the acquisition.

The completion of the acquisition is subject to certain customary conditions and regulatory approvals. The acquisition is expected to close by the end of 2018 or early 2019.

Financing
The upfront cash consideration payable will amount to USD 1,000 M (SEK 9.1 B) and the share consideration will consist of 24,193,092 newly issued Sobi shares, corresponding to a value of USD 500 M (SEK 4.5 B) based on the daily volume weighted average price paid for the Sobi common share on Nasdaq Stockholm during a period of five trading days immediately prior to entering into the agreement concerning the acquisition. The board of directors of Sobi will at closing of the acquisition exercise the authorisation granted by the Annual General Meeting in May 2018 to issue the Sobi shares.

The cash consideration will be funded by way of loans to be drawn from new credit facilities made available by BNP Paribas, Danske Bank, Skandinaviska Enskilda Banken and Svenska Handelsbanken. Jefferies International Ltd. is acting as sole financial advisor to Sobi and Latham & Watkins LLP and Mannheimer Swartling Advokatbyrå AB are acting as legal advisors to Sobi in connection with the transaction.

Following completion of the acquisition, Sobi's financial net debt is expected to be around SEK 6 B.

About Synagis
Synagis (palivizumab) is indicated for the prevention of serious LRTI caused by RSV in infants and young children at high risk of RSV disease. RSV is the most prevalent cause of LRTI among infants and young children. Synagis is a RSV F protein inhibitor monoclonal antibody (mAb) that acts as a prophylaxis against serious RSV disease.[5] It is the only medicine approved for the prevention of serious RSV disease.[6] AstraZeneca has a partnership agreement with AbbVie Inc. for the rights to Synagis outside the US, which will not be impacted by the proposed transaction.

About MEDI8897
MEDI8897 is a single dose extended half-life anti-RSV F mAb being developed for the prevention of LRTI caused by RSV in all infants entering their first RSV season[7] and children with chronic lung disease or congenital heart disease entering their first and second RSV season. MEDI8897 is being developed for the passive immunisation of a broad infant population and has been engineered to have a long half-life so that only one dose will be needed for the entire RSV season.[8] The current development plan includes initiation of a phase 3 study in healthy full-term and late pre-term infants. MEDI8897 has received Fast Track Designation from the US FDA in March 2015.

In March 2017, AstraZeneca and Sanofi Pasteur announced an agreement to jointly develop and commercialise MEDI8897. Under the agreement, AstraZeneca is responsible for all development activity through initial approvals, as well as manufacturing of MEDI8897, while Sanofi Pasteur leads commercialisation activities. The two companies share all costs and profits equally.

Investor and telephone conference
Financial analysts and media are invited to participate in a telephone conference to discuss the transaction at 14:00 CET. The event will be hosted by Sobi's CEO and President, Guido Oelkers, and the presentation will be held in English.

The presentation can be followed live, or afterwards on www.sobi.com.

To participate in the telephone conference, please call:

SE: +46 8 506 395 49
UK: +44 203 008 98 04
US: + 1 855 831 59 46

Click here to go to the live webcast.

After the live event the webcast will be available on-demand via the same URL.

Forward looking statements
This press release contains forward-looking statements, including statements regarding the potential benefits that may be derived from the acquisition of Synagis and the rights to MEDI8897, plans and expected timing with respect to the potential approval of MEDI8897 in the US, as well as potential future sales of Synagis and MEDI8897. 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. 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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[1] All figures in this press release in USD have been converted to SEK (and vice versa) at a USD/SEK exchange rate of 9.05, the average exchange rate as published by the Swedish Central Bank during a period of five business days prior to the announcement of the acquisition.

[2] PDUFA date 20 November 2018.

[3] Last twelve months

[4] Financial measure not defined according to IFRS (alternative performance measure). EBITA is earnings before interest, tax and amortisation

[5] Synagis (palivizumab) US prescribing information, May 2017

[6] Villafana, T. et al. Expert Review of Vaccines 2017

[7] The RSV season is usually from early autumn to late spring with a peak in winter.

[8] Zhu et al. Science Translational Medicine 2017

SOBI
RSV
Rare Diseases
haemophilia
Synagis
Related files:
wkr0006-3116692.pdf

> Guido Oelkers, CEO I am excited about adding Synagis to our portfolio as it remains the only product preventing RSV infection in this vulnerable patient group with a great medical need. The addition of Synagis will become an important strategic catalyst for Sobi’s future development and will form a powerful platform for growth in rare diseases.