ALK licenses rights to neffy®, the first approved adrenaline nasal spray for emergency treatment of allergic reactions (anaphylaxis)

November 09, 2024

ALK (*ALKB:DC / OMX: ALK B*) today announced that it has entered into a strategic license agreement with US-based ARS Pharmaceuticals, Inc. ("ARS Pharma", NASDAQ: SPRY). The agreement grants ALK exclusive global rights to the *neffy*® adrenaline (epinephrine) nasal spray, with exception of the USA, Australia, New Zealand, Japan and China. The deal delivers on key elements in ALK's new strategy Allergy+ and supports ALK's long-term financial ambitions.

- Needle-free, nasal delivery of adrenaline has the potential to become an important treatment option in anaphylaxis
- ALK also gains rights to future indications, including acute urticaria flares (in development)
- ALK to pay USD 145 million in upfront and additional future milestones and sales royalties

neffy® is the first and only approved needle-free emergency treatment for patients experiencing acute and potentially life-threatening allergic reactions. The European Commission granted EUR*neffy*® (the trade name for *neffy*® in the EU) market authorisation in the EU in August 2024. Furthermore, *neffy*® was approved by the US Food and Drug Administration also in August 2024. Submission for regulatory approval in Canada is planned for by the end of 2024.

ALK's CEO, Peter Halling, said: " *We are excited about the deal with ARS Pharma. It is an important step in ALK's strategic efforts to establish leading positions in anaphylaxis, food allergy, and new disease areas such as urticaria, supplementing our core allergy offerings. Emergency treatment of life-threatening allergic reactions has strong scientific and commercial ties to our existing portfolio and prescriber base. We are convinced that neffy® will transform anaphylaxis, benefitting patients at risk and leading to a significant expansion of the market."*

Exclusive rights to new indications
ARS Pharma is also developing its intranasal adrenaline (epinephrine) technology for the treatment of acute flares in patients with chronic urticaria, with plans to begin a Phase IIb clinical trial in 2025. The license agreement gives ALK exclusive rights for any new indications in the licensed territories. This aligns well with ALK's strategy, as it enables the ALK to take the first steps in addressing new adjacent disease areas.

Expanding market opportunities
ALK will initially focus on bringing *neffy*® to the markets in Europe and Canada, the world's second and third largest adrenaline autoinjector ("AAI") markets. In both markets, the product can be added to ALK's existing infrastructure and sales channels. The agreement also holds potential in other markets e.g. in Asia and Middle East.

Anaphylaxis requires immediate treatment with adrenaline (epinephrine), which today is predominantly administered intra-muscularly, including using AAIs, such as ALK's Jext ® pen. While adrenaline autoinjectors have been shown to be highly effective, there are well published limitations that result in many patients and caregivers delaying or not administering treatment in an emergency situation.

In Europe, ALK's main market, more than 20 million people are estimated to be at risk of experiencing anaphylaxis, however only approximately 2 million people are picking up their recommended rescue medication and many also fail to renew their prescription when needed. The combined value of the European and Canadian AAI markets is estimated at approximately DKK 1.6 billion (2023) and has been growing steadily in recent years.

Portfolio approach
In line with its Allergy^{+} strategy, ALK is committed to helping patients at risk of anaphylaxis with a portfolio of innovative solutions with multiple administration forms. ALK will continue to market the adrenaline autoinjector Jext® in Europe and several international markets. ALK will also continue the in-house Genesis project to develop a next-generation adrenaline autoinjector.

CEO Peter Halling said: "*While we believe that nasal delivery of adrenaline could become an important new standard of care in anaphylaxis management over the next decade, we also acknowledge that changing long-standing clinical practices may take time. Therefore, we will maintain a portfolio approach to meet the diverse needs of patients and prescribers."*

Financials considerations
The agreement supplements ALK's financial ambitions and is expected to diversify the long-term revenue growth. ALK estimates that *neffy*® holds a long-term annual peak sales potential in anaphylaxis of up to DKK 3 billion in the licensed territories. There may be substantial upsides to this potential from new indications in e.g. urticaria.

Under the agreement, ARS Pharma is entitled to receive an upfront payment of USD 145 million (DKK 1 billion) from ALK. Furthermore, ARS Pharma may receive up to USD 320 million (DKK 2.2 billion) related to regulatory and commercial milestones, potentially over the next 15+ years as well as tiered royalties in the teens on future sales. ARS Pharma will supply finished goods to ALK, while ALK will be responsible for local market access, marketing and sales.

ALK will finance the upfront payment out of its available cash and existing credit facilities, and equally plans to finance future milestone payments and royalties out of ALK's available cash. Following settlement of the upfront payment, ALK's net debt to EBITDA ratio for 2024 will expectedly still be below 1.

The first launches are expected to take place in Europe in 2025 once local market access negotiations are completed. The license agreement is expected to contribute to revenue growth from 2025 onwards, with an initially limited impact, and is projected to be earnings accreditive within a few years. The deal is therefore expected to support ALK's long-term financial ambitions, which remain unchanged.

This announcement does not change ALK’s revenue and earnings outlook for 2024. ALK’s ambition of achieving a 25% EBIT margin in 2025 remains unchanged.

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ALK is hosting a conference call for analysts and investors at 8.00-8.30 a.m. (CET) on Monday 11 November 2024 regarding the licence agreement with ARS Pharma. The conference call will be audio cast on https://ir.alk.net where the relevant presentation will be available shortly before the call begins.

To register for the conference call, please use this link: https://dpregister.com/sreg/10194511/fdfa1c19d7 and follow the registration instructions. You will receive an email from diamondpass@choruscall.com with dial-in details, including a passcode and a pin code. Please make sure to whitelist diamondpass@choruscall.com and/or check your spam filter. We advise you to register well in advance and to call in before 7.55 a.m. (CET).

About ALK
ALK is a global specialty pharmaceutical company focused on allergy and allergic asthma. ALK markets allergy immunotherapy treatments and other products and services for people with allergy and allergy doctors. Headquartered in Hørsholm, Denmark, ALK employs around 2,900 people worldwide and is listed on Nasdaq Copenhagen. Find more information at www.alk.net.

About neffy®
neffy® is a compact nasal spray, designed to provide rapid absorption of adrenaline (epinephrine). The solution is simple to use, non-invasive and more convenient for patients to carry and use, and it offers longer shelf-life and superior temperature stability compared to existing adrenaline pens (AAIs). In Europe, it is currently indicated for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. Subject to approval in Europe, a dose for children weighing 15-30 kg is expected to be available from late 2025.

About ARS Pharma
ARS Pharmaceuticals is a biopharmaceutical company dedicated to empowering at-risk patients and their caregivers to better protect patients from allergic reactions that could lead to anaphylaxis. The Company is commercializing neffy® 2 mg (trade name EURneffy® in the EU) (previously referred to as ARS-1), an epinephrine nasal spray indicated in the U.S. for emergency treatment of Type I allergic reactions, including anaphylaxis, in adult and pediatric patients who weigh 30 kg or greater, and in the EU for emergency treatment of allergic reactions (anaphylaxis) due to insect stings or bites, foods, medicinal products, and other allergens as well as idiopathic or exercise induced anaphylaxis in adults and children who weigh 30 kg or greater. For more information, visit www.ars-pharma.com.

Forward-looking Statements
This announcement contains forward-looking statements, including forecasts of future revenue and operating profit as well as expected business-related events. Such statements are naturally subject to risks and uncertainties as various factors, some of which are beyond the control of ALK, may cause actual results and performance to differ materially from the forecasts made in this announcement. Such factors include but are not limited to general economic and business-related conditions, including legal issues, uncertainty relating to demand, pricing, reimbursement rules, regulatory approvals, partners' plans and forecasts, fluctuations in exchange rates, competitive factors and reliance on suppliers. Additional factors include the risks associated with the sourcing and manufacturing of ALK's products. ALK undertakes no obligation to publicly update or revise forward-looking statements to reflect subsequent events or circumstances after the date made, except as required by law.

Attachment

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