

## **Ablynx And AbbVie Sign Global License Agreement For anti-IL-6R Nanobody, ALX-0061, To Treat Inflammatory Diseases**

**- Anti-IL-6R Nanobody, ALX-0061, to be developed in rheumatoid arthritis and systemic lupus erythematosus**

**- Ablynx to receive an upfront payment of \$175 million and up to \$665 million in potential total milestone payments plus royalties on net sales**

*Ablynx will host a webcast presentation today at 16h CET, 10 am ET*

GHENT, Belgium and NORTH CHICAGO, Illinois, Sept. 23, 2013 -- Ablynx [*Euronext Brussels: ABLX*] and AbbVie [*NYSE: ABBV*] today announced that they have entered into a global license agreement to develop and commercialize the anti-IL-6R Nanobody, ALX-0061, to treat inflammatory diseases. ALX-0061 is Ablynx's proprietary anti-IL-6R Nanobody that successfully completed a Phase IIa study in February 2013 reporting strong efficacy and safety data in patients with moderately to severely active rheumatoid arthritis (RA) on a stable background of methotrexate.

Under the terms of the agreement, Ablynx will be responsible for completing Phase II clinical development in both RA and systemic lupus erythematosus (SLE). Upon the achievement of pre-defined success criteria, AbbVie will exercise its right to in-license ALX-0061 and be responsible for subsequent Phase III clinical development and commercialization. Ablynx will retain an option for co-promotion rights in Belgium, the Netherlands and Luxembourg. Ablynx will receive an upfront payment of \$175 million, which will partly be used to fund the next phases of clinical development of ALX-0061. Upon achievement of certain development, regulatory, commercial and sales-based milestones, Ablynx will be eligible to receive additional milestone payments totalling up to \$665 million as well as double-digit tiered royalties on net sales upon commercialization.

"This deal represents a major milestone for Ablynx and confirms both the potential value of ALX-0061 and the ability of our Nanobody technology to generate clinical candidates with very exciting potential," said Edwin Moses, Ph.D., chairman and chief executive officer, Ablynx. "It also demonstrates that we are delivering on our business model of strategic partnering for the development and commercialization of selected programs within our pipeline. We truly believe that AbbVie's significant expertise in rheumatology aligns us with the ideal partner to further progress the development of ALX-0061 and to ensure we maximize the potential of this asset."

Dr. Moses added, "the combined clinical expertise of AbbVie and Ablynx will allow us to progress with the rapid development of ALX-0061, with the current plan being the initiation of various clinical trials in both RA and SLE during the course of 2014 and 2015. We look forward to working together with AbbVie to potentially develop a successful therapy for patients suffering from chronic inflammatory conditions and to making a real difference to the quality of their lives."

"This agreement is further evidence of AbbVie's commitment to pursue novel treatment options for autoimmune diseases," said Scott Brun, M.D., vice president, pharmaceutical development, AbbVie. "Anti-IL-6 antibodies are a proven mechanism of action for autoimmune diseases and ALX-0061 has shown potential in a Phase IIa clinical trial in RA. We are looking forward to working with Ablynx to develop a potentially new and effective therapy for patients suffering from serious chronic conditions such as RA and SLE."

### **About ALX-0061**

ALX-0061 targets the interleukin 6 pathway via its IL-6 receptor (IL-6R), which plays a key role in the inflammation process in RA. ALX-0061 has been designed to become a best-in-class therapeutic. Its small size (26kD) may potentially allow ALX-0061 to penetrate more effectively into tissues. The potent, monovalent interaction of the molecule with its target reduces the possibility of off-target effects. Its binding to human serum albumin prolongs the *in vivo* half-life of the product and can lead to improved trafficking to areas of inflammation. The Nanobody has a very strong affinity for soluble IL-6R which should ensure fast target engagement and could result in a fast onset of effect. ALX-0061 appears to benefit from the general Nanobody characteristic of having a very low immunogenic potential.

### **About RA and SLE**

RA is characterized by chronic and progressive joint inflammation that typically results in permanent, debilitating tissue damage, which is further compounded by joint deformation. The condition is associated with lower quality of life, premature death, disability, and unemployment. It is estimated that up to 1 percent of the adult population worldwide suffer from RA.

SLE is a complex, multi-organ, autoimmune disorder characterized by the production of pathogenic autoantibodies and tissue deposition of immune complexes, which result in widespread tissue damage. Although the etiology of SLE is not fully understood, multiple genetic, environmental, and hormonal factors have been implicated in its development. The disease displays a broad variety of symptoms and highly variable clinical features, including systemic, cutaneous, renal, musculoskeletal, and haematological manifestations.

Approximately 5 million people worldwide suffer from a form of lupus and 90 percent of people diagnosed are women.

### **Conference call and webcast presentation**

The Ablynx management team will host a conference call and webcast during which the licensing deal with AbbVie will be presented, followed by a Q&A session. This event will be held today, Sept. 23, 2013 at 4.00 pm CET/ 10 am ET. The conference call will be webcast live and may be accessed on the home page of the Ablynx website at [www.ablynx.com](http://www.ablynx.com). If you would like to participate in the Q&A, please dial +32 (0)2 620 0138, confirmation code 7195500. Shortly after the call, a replay of the webcast and the presentation used in connection with the conference call webcast will be available on Ablynx's website.

### **About Ablynx**

[Ablynx](http://www.ablynx.com) is a biopharmaceutical company engaged in the discovery and development of [Nanobodies®](#), a novel class of therapeutic proteins based on single-domain antibody fragments, for a range of serious human diseases, including inflammation, haematology, oncology and pulmonary disease. Today, Ablynx has approximately [25 programs in the pipeline](#) and six Nanobodies at clinical development stage. Ablynx has ongoing research collaborations and significant partnerships with major pharmaceutical companies including Boehringer Ingelheim, Merck Serono, Novartis, Merck & Co and AbbVie. The Company is headquartered in Ghent, Belgium. More information can be found on [www.ablynx.com](http://www.ablynx.com).

### **About AbbVie**

AbbVie is a global, research-based biopharmaceutical company formed in 2013 following separation from Abbott. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. In 2013, AbbVie employs approximately 21,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit [www.abbvie.com](http://www.abbvie.com).

### **Ablynx forward-looking statements**

*Certain statements, beliefs and opinions in this press release are forward-looking, which reflect the Company's or, as appropriate, the Company's directors' current expectations and projections about future events. By their nature, forward-looking statements involve a number of risks, uncertainties and assumptions that could cause actual results or events to differ materially from those expressed or implied by the forward-looking statements.*

*These risks, uncertainties and assumptions could adversely affect the outcome and financial effects of the plans and events described herein. A multitude of factors including, but not limited to, changes in demand, competition and technology, can cause actual events, performance or results to differ significantly from any anticipated development. Forward looking statements contained in this press release regarding past trends or activities should not be taken as a representation that such trends or activities will continue in the future. As a result, the Company expressly disclaims any obligation or undertaking to release any update or revisions to any forward-looking statements in this press release as a result of any change in expectations or any change in events, conditions, assumptions or circumstances on which these forward-looking statements are based. Neither the Company nor its advisers or representatives nor any of its or their parent or subsidiary undertakings or any such person's officers or employees guarantees that the assumptions underlying such forward-looking statements are free from errors nor does either accept any responsibility for the future accuracy of the forward-looking statements contained in this press release or the actual occurrence of the forecasted developments. You should not place undue reliance on forward-looking statements, which speak only as of the date of this press release.*

### **AbbVie forward-looking statements**

*Some statements in this news release may be forward-looking statements for purposes of the Private Securities Litigation Reform Act of 1995. The words "believe," "expect," "anticipate," "project" and similar expressions, among others, generally identify forward-looking statements. AbbVie cautions that these forward-looking statements are subject to risks and uncertainties that may cause actual results to differ materially from those indicated in the forward-looking statements. Such risks and uncertainties include, but are not limited to, challenges to intellectual property, competition from other products, difficulties inherent in the research and development process, adverse litigation or government action, and changes to laws and regulations applicable to our industry. Additional information about the economic, competitive, governmental, technological and other factors that may affect AbbVie's operations is set forth in Item 1A, "Risk Factors," in AbbVie's 2012 Annual Report on Form 10-K/A, which has been filed with the Securities and Exchange Commission. AbbVie undertakes no obligation to release publicly any revisions to forward-looking statements as a result of subsequent events or developments, except as required by law.*

SOURCE AbbVie Inc.

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