

## **Organon continues with the development of asenapine**

**Arnhem, The Netherlands, November 28, 2006 — Organon has decided to continue with the development of asenapine. This follows on from the decision taken by Organon and Pfizer to discontinue their collaboration in the further development of asenapine, a new drug candidate for the treatment of schizophrenia and acute mania associated with Bipolar I Disorder.**

The results of the final Phase III clinical trial with respect to schizophrenia, which were recently received, were positive. This is in addition to the previous positive data on safety and tolerability for this indication. Organon will now assess if further clinical trials are necessary. Organon has data on efficacy, safety and tolerability for the treatment of Bipolar I Disorder and the positive data on the treatment of schizophrenia.

Pfizer's decision to discontinue its participation in the asenapine development program is an outcome of a commercial analysis of the compound as a part of its overall portfolio.

The interim assessment of the Phase III trial results made available in October led to the caution that the results might not be sufficiently conclusive to warrant an NDA filing with the FDA in 2007. This has not changed.

Toon Wilderbeek, the Akzo Nobel Board member responsible for Pharma, who is also President of Organon, said today: "The satisfactory results of the final Phase III clinical trial – in the context of the complete Phase III clinical trial data set for asenapine – is an important milestone in the development of asenapine. We have now completed a crucial phase of the program and we will assess if further trials might still be required in order to be able to submit a strong NDA file."

He continued: "We are pleased to now have the opportunity to pursue a go-to-market strategy for asenapine which is more closely aligned with our planning and positioning for this product candidate. We will evaluate whether we need a partner to commercialize asenapine in selected geographic areas in due course. Although Organon is disappointed with the withdrawal, the company appreciates the positive contribution Pfizer has made to the development of asenapine."

Willem de Laat, Organon's Executive Vice-President Medical Affairs, added: "Patients treated for schizophrenia and bipolar disorder are frequently faced with significant unmet needs. Compliance remains an issue for the majority and many switch to other medication for a variety of reasons – including tolerability, side effects and administration forms. Therefore it is important to offer other options that address a patient's real-life needs and that will bring relief to those seeking alternative treatment."

The Phase III trial program for the initial NDA submission consisted of schizophrenia and bipolar mania trials involving more than 2,000 and 950 patients, respectively. Asenapine, a fast-dissolving, novel psychopharmacologic agent with a unique human receptor signature, was shown to be effective in two out of four short-term schizophrenia studies, two short-term bipolar mania studies with a nine- week extension. One schizophrenia study failed (both asenapine and the active comparator did not differentiate from placebo) and one study was negative for asenapine on its primary endpoint (asenapine did not discriminate at end point from placebo, while the active comparator did).

The safety profile of asenapine, derived from a long-term 1,200 patient safety study and efficacy studies, is in line with the profile as found in phase II studies, i.e. minimal effects on weight gain, QTc, metabolic parameters and liver parameters, and is considered to be adequate for the treatment of schizophrenic and bipolar patients. Details of the efficacy and safety results will be communicated during scientific meetings in due course.

Pfizer will return all product rights, intellectual property and data to Organon and make orderly transitions during 2007.

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**Note for the editor**

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