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Emotra: Comments on questions about EUDOR-A

Emotra has learnt that communications from an individual researcher have been disclosed to the financial market. Yesterday and this evening, Emotra has been receiving questions from concerned shareholders about our open, naturalistic, multi-centre study, EUDOR-A. We therefore intend to address this situation through this press release.

A working document was written at the so-called consensus meeting held in Rome at the end of March 2017. The purpose of this document was to help the meeting reach a consensus in their opinion of EDOR. The meeting delegates agreed that this document should not be used externally and Emotra has never used it in its marketing.
Emotra has learnt that an individual researcher, on his own initiative, has written and disseminated a revised so-called consensus statement that purports to summarise the conclusions which can be drawn from the results of our EUDOR-A study. Emotra must therefore point out that no new consensus meeting has been held and that this new statement should be interpreted as that individual researcher's personal views.

The decisions to launch EDOR® as a supplement to routine practice when assessing suicide risk was made by Emotra's board of directors following a review held at a consensus meeting in Rome at the end of March 2017. However, we need to point out that any such decision is Emotra's sole responsibility, as is the responsibility for ensuring that EDOR complies with all applicable functional and product-safety requirements.

During our continued efforts, the company has not encountered any reason to doubt the solid scientific documentation which shows that EDOR securely identifies hyporeactivity in depressed patients, and that the suicide risk among these patients is significantly higher than for other patient groups.

In our quarterly report covering the period January–March 2017, which was published on April 26, 2017, Emotra stated the following:

- The total ratio of documented suicides in EUDOR-A is a record low and dramatically lower than in previous blind studies.
- In all previous studies, the suicide rate has been distinctly higher among hyporeactive patients than among normally reactive patients.
- Despite a strong reduction in the number of suicides in the hyporeactive group in EUDOR-A, the suicide rate for the hyporeactive group is clearly higher than for the normally reactive patient group.
- A considerably higher suicide attempt rate was documented in the hyporeactive group compared with the normally reactive group.

Facts about the EUDOR-A study:

- EUDOR-A was an open, naturalistic study and therefore was not carried out as a blind study. It did not encompass any control groups or comparative data.
- The consequences of this approach are that the involved clinics were aware of the analysis results, and many have treated their study patients as high-risk patients. This in turn means that we cannot make any statements about the efficacy of EDOR as a test method or about the strength of hyporeactivity as a marker for suicide risk.

- The same reasoning applies to the traditional, structured risk assessments that were carried out.
- As far as Emotra is concerned, our EUDOR-A study produced a lot of valuable data, among this the ability to draw a connection between hyporeactivity and previously reported suicide attempts.
- The connection with previous suicide attempts has been an important point in our discussions with the clinics that have decided to implement EDOR in their clinical practice.

The preliminary findings that Emotra have previously disclosed in press releases and financial reports rely on specific facts and these facts have not changed during the long process of repeated statistical analyses and the writing of a paper.

It is important to note that any recommendations to use a certain method in clinical practice are made at the national level within that country's relevant healthcare regulatory framework. Each individual healthcare clinic or organisation then makes an independent decision based on the available data and other considerations. Since Emotra has not used the consensus statement in our marketing efforts, the clinics presently using EDOR in their regular practice have based their decisions on existing information, among which the Odds Ratio article published in September 2018 has been the most convincing argument.

Daniel Poté, our CEO, says:
After a long wait, a paper manuscript is now ready and will be sent for publication in a scientific journal. Since this article will be reviewed and may undergo significant changes before publication, the company sees no reason to comment on its contents before it has been accepted. As we have already clarified, we have started and will with time continue to further refine our market introduction strategy. The feedback from customer meetings has shown a strong interest in the product and a large need for modern, technical tools in daily practice. EDOR provides unique, objective and easy-to-understand information that enables a more comprehensive risk assessment of depressed patients.

Continued research efforts have further strengthened previous strong clinical documentation. We have been able to demonstrate that the suicide risk, according to the aggregated results of blind studies, is 25 times higher among hyporeactive patients than among normally reactive patients. Other studies have shown that hyporeactivity is also connected to an increased risk for patients with other psychiatric disorders.

Emotra's long-term focus is to continue documenting EDOR in order to further validate the benefits of using the method in clinical practice. Recent years' research has shown strong opportunities for using Emotra's method in clinical assessment and treatment of depressed patients.

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