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# Consensus meeting supports plans to launch EDOR®

**The Emotra clinical multicentre study, EUDOR-A, which was started during the spring of 2014, has been finalized. The study clearly demonstrates a lower number of suicides in comparison with previous studies, particularly and statistically significantly in the hyporeactive group. During the meeting between participants in the study in Rome the last two days, 29th to 30th of March, the results were carefully analysed. A consensus was reached and it was agreed to endorse the plans to launch EDOR® in Europe.**
**The study was organized as a naturalistic and non-blinded study, i.e., the clinical centres were informed about the test results to be used according to everyone's wishes. The objective was to investigate the effects of a broad use of the test of depressed patients, with a variety of secondary diagnoses and somatic diseases, also in old patients, at many clinical centres.**

The analyses of the results show with great statistical power that the clinical teams have taken the test result into consideration and in general increased the risk level for patients that have been tested hyporeactive. The number of suicides in the hyporeactive group has been reduced substantially. Only three hyporeactive suicides were documented. According to calculations based on results from all previous studies, many more suicides would have occurred in this group, if the study had been blinded. In the reactive group, the number of suicides was very low in agreement with the expectations from previous studies.
In a study by Thorell and a group of German researchers with 783 tested patients in Ravensburg, with a follow-up period of 1- 5 years, a strong correlation between hyporeactivity and suicide was demonstrated. The Ravensburg study confirmed all observations from previous smaller studies. Because of the previously demonstrated strong relationship between hyporeactivity and suicide, it was decided to make the European multicentre study, EUDOR-A, a non-blinded naturalistic study. With such a clear picture of how hyporeactivity correlate to suicide, the participating clinical centres and as many local ethical committees did not consider it ethically acceptable, to leave the patients and clinical staff without information about the test results.
A direct comparison between EUDOR-A and all the previous studies indicates that the substantial reduction of the number of suicides in the recently finalised multicentre study can be explained by the fact that the clinical centres have used the test results in the risk assessment and to a large extent have adjusted the suicide preventive actions in accordance with this.
A large majority of the clinical centres witnessed that they had increased the suicide preventive actions for patients that were tested hyporeactive.
The consensus meeting did not exclude the possibilities for additional reasons for the low number of suicides in the study; A longer follow-up period could possibly contribute to additional suicides. The fact that the follow-up has been organized within the frame of a clinical study may have had effect on the clinical team's procedures as well as the patient's suicide behaviour. A study with considerably larger patient group would possibly result in a higher proportion of suicides.

With respect to all available data from previous studies and the present multicentre study, the consensus meeting decided to back up the decision to launch EDOR® to the psychiatric specialist clinics in Europe, as a supplement to the clinical professional's routine work in assessments of suicide risk broadly among depressed patients. Emotra will market the method as a instrument to detect hyporeactive patients. The plans have never been to claim that EDOR® as a standalone instrument should replace the traditional assessment techniques. The most important advantage that EDOR® brings to the care givers is an objective and complementary technique to the subjective methods that is still at use in the clinical routine procedures.

Additional advantages that were emphasized by the participants in the study were the easy usage, the fast test procedure, that EDOR® was well accepted and tolerated by the patients, the non-invasive and risk free approach and the short time it takes to get the final analyses from Emotra.

The study results support the conclusion that the method can be used independently of physical and secondary psychiatric diagnoses as well as demographic variations, including elderly patients. This allows a very broad indication of EDOR® in the specialist psychiatric care for suicide prevention among depressed patients.

Parallel to the market introduction, Emotra will initiate an extensive patient follow-up system, like a Phase IV study in the pharmaceutical industry. The purpose with this initiative is to study the reduction of suicides at clinics using EDOR® in comparison with clinics that do not and to collect data from many more tests, which in a longer perspective could increase the deeper understanding of these difficult and very complex medical issues.

The consensus meeting stated, that further analyses of the study results of EUDOR-A, and additional studies should be accomplished in order to better understand the role of hyporeactivity in relation to suicidal behaviour.

All centres except from two in Sweden, on in Hungary and one of the two centres in Poland participated in the consensus meeting. The opinion among the absent centres remain to be collected.

The scientific reports and deepened analyses of the results of the EUDOR-A study will be done in forthcoming publications.

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*This information is the type of information that Emotra AB is legally obliged to publish in accordance with the EU market abuse regulation and the Securities Market Act. This information was submitted for publication on March 31, 2017 under the above contact's supervision.*

***Emotra AB (publ)** is a medical technology company that carries out research, development, clinical studies and marketing in the area of suicide prevention. The Company's method, EDOR®, is a proprietary, objective and quantitative diagnostic, psychophysiological test for detecting hyporeactivity in patients suffering from depression. During the test, the patient listens to a series of audio signals. The patient's response, in the form of very small changes in dermal electric conductivity, is measured and analysed. This extremely sensitive and specific test of suicidal risk has been developed as the result of research.*