

Press release from Emotra AB (publ)  
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## Conclusions from our baseline analysis of EUDOR-A

**As previously notified, Emotra AB has completed the testing phase of its ongoing clinical multi-centre study, EUDOR-A. A total of 1,544 patients have been tested and analysed. Our analysis of the baseline material shows a strong conformance with previous observations. Those differences that we have found can be explained by the fact that EUDOR-A is a significantly larger study than our previous ones and that many of the patients have considerably more complex illness situations than previously tested patients. In the second stage of our study, the patients will be monitored and checked for a 12-month period after testing. This stage of our study will be completed on March 10, 2017. Lars-Håkan Thorell has been invited to become a member of The European College of Neuropsychopharmacology (ECNP).**

The submission of tests in our multi-centre study, EUDOR-A, has progressed at a high rate, with 1,544 patients being tested with EDOR™ since the trial was launched in the autumn of 2014.

Research centres and clinics in a large number of European countries have participated in the first stage of our EUDOR-A study by regularly submitting test data to Emotra for analysis. All of this clinical patient data has now been compiled in Rome into a *clinical database*. At the same time, and without knowledge of the data in the clinical database, all of the test results were compiled in an *EDOR™ Test database* in Linköping. These two databases were then merged into a single, large *BASELINE DATABASE*. This work enabled an in-depth study of the occurrence of hyporeactivity in different patient categories as well as the connection between hyporeactivity and previous suicide attempts. The data analysis from the first stage of our study will result in a “Baseline publication”.

In the table below we present our results so far among the 1,544 patients that were tested with EDOR™ Test in our EUDOR-A study. The material in our EUDOR-A study differs in several aspects from the material in earlier studies of hyporeactivity. This is intentional. EUDOR-A is a multi-centre study in a naturalistic environment. This includes patients with secondary psychiatric diagnoses (except substance abuse), patients with somatic ailments, patients who are over 65 years of age, and patients undergoing a wide spectrum of medical and psychological treatments.

The term “self-injury disorder” refers to all types of injuries that a person intentionally inflicts upon himself/herself and which require medical attention or are fatal. In our baseline material, we have been able to discern that approximately one third of the patients have shown signs of self-injury disorder. This is an exceptionally large proportion of the tested patients; much higher than the share who were expected to be suicidal. A suicide attempt essentially denotes an action with the intention of dying. In other words, only a small proportion of self-injury incidents are actual suicide attempts. The intention of taking one’s own life has been shown to be very hard to determine. For this reason, it is not possible to present any concrete connection between the test results and previous suicide attempts. Nor should we expect any connection between hyporeactivity and self-injury disorder, since the vast majority of the patients who displayed this disorder do not belong to the suicide-risk group.

Our main goal with EUDOR-A is to prove the connection between hyporeactivity and the risk of suicide attempts. The suicide risk for an individual patient can only be determined after a follow-up of all the tested patients. Another goal of this study is to identify those patient groups whose illness situations are so complex or whose ongoing medical treatment make it more difficult to draw any clinical conclusions based on EDOR™ test results. It is our study management’s opinion that the 1,544 tested patients constitute a sufficient basis to ensure the fulfilment of our study’s purposes.

In the below table we present the results of those analyses we have carried out so far.

**Table**

| Occurrence of hyporeactivity in relation to | is:                                     | Comments:                          |
|---|---|------------------------------------|
| age   | confirmed independent                   |                                    |
| gender                                      | confirmed independent                   |                                    |
| severeness of depression                    | confirmed independent                   |                                    |
| individual symptoms                         | confirmed independent                   |                                    |
| bipolar disorder                            | confirmed higher than others            |                                    |
| in-patient care                             | confirmed higher than for out-patients  |                                    |
| clinically evaluated risk                   | certain conformance confirmed           |                                    |
| self-injury disorder <sup>1</sup>           | lower (= normal reactivity most common) | Indicative of anxiety <sup>1</sup> |
| suicide                                     | –                                       | Can only be tested after follow-up |

<sup>1</sup> The vast majority of patients with self-injury disorders do not intend to kill themselves. The results comprise objective proof that this group suffers from increased anxiety. This confirms previously presented results from 2001 by Thorell and Moskwa and constitutes an important observation for the understanding of self-injury disorder and suicide prevention.

This table clearly shows that the material in our EUDOR-A study provides results that are consistent with earlier research. We could not ask for better results on a baseline level. The results show that the occurrence of hyporeactivity is completely independent of such factors as age, gender, severeness of depression and individual symptoms. They also show that hyporeactivity is most common in patients with bipolar disorder and more common among in-patients than out-patients. All of these results confirm previous observations. We have observed relatively high conformance between those patients who tested positive for hyporeactivity and previous clinical evaluations of suicide risk.

This high conformance with previous results is the most important conclusion that can be drawn from the baseline material. It shows that the prevalence of hyporeactivity in EUDOR-A is completely in line with the expectations that have arisen through earlier study results, which raises good hope that the final study results after a full year's follow-up will also meet high expectations.

In the second stage, the patients will be monitored for signs of suicidal behaviour. This stage of our study will be finalised by March 10, 2017. After that we will move on to analysing the test results. We will be comparing the frequency of failed and successful suicide attempts among those patients we identified as hyporeactive and those who showed normal reactivity. After that, the material will be processed statistically. We have already secured the services of statistics experts and they have been continuously monitoring the progress of our study. They should therefore be able to begin their calculations with a minimum of delay. After this, we will gather all of the participating research groups to a consensus meeting to evaluate the results and compose a joint statement that everyone approves.

The Company plans to launch the product internationally once the study has been completed and we plan to base our marketing information to a large extent on the clinics' consensus statement. Our market launch will initially focus on the markets that were represented by clinics in our study, and the Company's strategy is to start generating significant demand by reaching out to specialised

psychiatric care clinics with information about EDOR™ and what our study has shown. Our idea is to let the involved clinics to a large extent act as ambassadors to the specialised care sector.

Our ambition is that our chosen strategy will lead to a quick market penetration. The Company's goal is to achieve stable and rapid growth under profitable conditions within two years of the product launch. The Company's organisation will grow in pace with our sales so that we can maintain maximum control of our costs in all stages of this process.

#### **Lars-Håkan Thorell, member of ECNP**

The strong support that leading European psychiatric researchers have shown for Emotra and EDOR™ has led to the invitation of Lars-Håkan Thorell, the inventor of EDOR™ and Emotra's Research Manager, to become a member of the ECNP's (European College of Neuropsychopharmacology) suicide research section. Receiving such an invitation is a great honour and Lars-Håkan Thorell has accepted this membership. Judging by the contacts the Company has had with ECNP, this membership is the first step in Emotra's future collaboration with this European research organisation. Emotra already enjoys an in-depth collaboration with the other important scientific organisation in this area, EPA-SS, the European Psychiatric Association's Suicide Section.

In October, 2016, Lars-Håkan Thorell will be presenting his research at a large international conference on bipolar disorders in Chicago, USA. Thorell has been invited as one of the keynote speakers at this event.

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***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.*

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