

COMPASS Pathways news | December 2018 issue

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As 2018 draws to a close, we reflect on another busy year and share our highlights of the last few months with you.

We have continued to make good progress since our last update: beginning patient recruitment in five of our treatment-resistant depression trial sites; gaining approval and breakthrough therapy designation for our trial from the US Food and Drugs Administration (FDA); reaching the halfway point in our healthy volunteers study; securing £25m in funding; and convening the first meeting of our Scientific Advisory Board.

We receive emails from so many people who are suffering, or are close to someone who is suffering, with treatment-resistant depression. These stories motivate us all every day at COMPASS. Our mission – accelerating patient access to evidence-based innovation in mental health – remains critical while the incidence of depression and other mental health challenges continues to rise. More than 100 million people have treatment-resistant depression (TRD) and depression remains the leading cause of disability worldwide. We simply cannot ignore this and are determined to do our part in alleviating it. We remain focused on developing Psilocybin Therapy for the safe and effective treatment of patients with depression, for whom existing treatments do not work.

Treatment-resistant depression (TRD) trial

Our phase IIb clinical trial for Psilocybin Therapy for treatment-resistant depression has now been fully approved in the UK, the Netherlands, Canada, the US, and Ireland. Further approvals are expected in additional European countries over the next few months. Patient recruitment has begun in trial sites in the UK, the Netherlands, and Ireland.

Treatment room in TRD trial

In October, we held an Investigator Meeting and therapist training for our North American sites. These sites, across

the US and Canada, will begin patient recruitment in the first quarter of 2019.

Breakthrough therapy designation

In October, the FDA awarded breakthrough therapy designation to Psilocybin Therapy as a potential treatment for treatment-resistant depression. Breakthrough therapy designation is given to therapies for which preliminary clinical evidence shows a potential substantial improvement over available treatments. This is a strong endorsement for the potential of Psilocybin Therapy and one that will increase the chances of getting this treatment to the many people suffering with treatment-resistant depression. The designation means the FDA will be committed to supporting our clinical development programme and will work closely with us to ensure the process is as efficient as possible.

Breakthrough therapy designation is also a mark of recognition for the vision and extraordinary work of generations of psychedelic researchers and therapists before us.

Healthy volunteers study

Our healthy volunteers **study** is halfway through. The study is taking place at the Institute of Psychiatry, Psychology and Neuroscience (IoPPN) at King's College London, and explores the short- and long-term effects of medium- and high-dose psilocybin on social, emotional and cognitive functioning, as compared to placebo. The study also provides a platform for therapists in our TRD trial to support volunteers under the guidance of our expert therapists, as part of their professional training.

We expect to complete the healthy volunteers study in the first half of next year and to report findings in the second half.

Fundraising

We have completed our Series A financing round, raising £25m from a group of investors who share our commitment to bringing Psilocybin Therapy to as many patients as possible. The funds will enable us to complete our healthy volunteers study and phase IIb trial.

Scientific advisory board

In November, we held the inaugural meeting of our scientific advisory board (SAB), a group comprising experts in neuroscience, psychiatry, neuropsychopharmacology, and regulatory science. With our SAB, we have begun to refine our clinical development plans and to explore ideas for additional studies in the future, to complement our work on treatment-resistant depression.

Looking ahead to 2019

Our progress and our achievements have been made possible by the dedication of our strong in-house team.

Our team continues to grow, and we are delighted that Hans Eriksson will be joining COMPASS in January as our new Chief Medical Officer. Hans was most recently Senior Director, Clinical Research for Depression and Pediatrics at H Lundbeck. He brings a wealth of experience in taking medicinal products to patients and we look forward to working with him as our clinical development programme continues. Ekaterina Malievskaia, COMPASS co-founder and current Chief Medical Officer, will take a more strategic role from 2019, overseeing R&D and our therapist training programme.

We enjoy a vibrant internship programme at COMPASS. This year we had 11 interns from leading European and US academic institutions, spending on average three months at COMPASS, and learning and contributing to different teams – from clinical trial management and operations, to market access, business development and fundraising. We will continue this programme in 2019.

In addition to our talented colleagues and enthusiastic interns, we are fortunate to work with an exceptionally skilled and dedicated group of advisors and partners. We are all excited about the next few months and each step that takes us closer to our goal of accelerating access to help patients.

In 2019, we will complete and report out on our healthy volunteers study. We also aim to complete recruitment for our treatment-resistant depression trial. While we are not pre-empting what the science will tell us or what the results of the trial will be, we have started the critical and complex work on market access strategy, so that we can be ready to bring Psilocybin Therapy to patients without delay and in a way that makes it accessible and affordable to as many people as possible.

In the spirit of the holiday season and on behalf of our board members, scientific advisors, investors and supporters, COMPASS has made a donation to **One Mind**, a US-based non-profit organisation dedicated to accelerating research in mental health through the principles of large-scale open science. We support and share their goals which are very much aligned to the work we are doing at COMPASS.

With only a few days left in 2018, we wish everyone a very happy holiday season, and all the best for the New Year.

Your feedback

If you'd like to know more about what we are doing or have comments about COMPASS Pathways News, please get in touch with us at info@compasspathways.com.