NEWS RELEASE

COMPASS Pathways news | December 2017 issue

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END OF YEAR UPDATE

December 2017

Dear friends, supporters and colleagues,

The holiday season is approaching, and as we begin dreaming of festive treats and spending the holidays cocooned in thick duvets with a cup of hot chocolate in hand, I would like to reflect on our journey this past year and share a few 2017 highlights.

Trial designed by multidisciplinary team
In February, we held our treatment-resistant depression (TRD) trial design meeting at London's Home House, assembling experts and leaders from the fields of psychiatry, pharma development, neuroscience and psychedelics. Those of you who were there will remember the spirit of collaboration and mutual learning, and how energised we all were by the novelty and promise of the approach.

EMA scientific advice completed
Only a few months later we presented our trial design and clinical development programme to the European Medicines Agency (EMA), at a scientific advice meeting led by the head Italian regulator and psychiatrist, Professor Luca Pani. We were impressed by how deeply European regulators were thinking about our proposed approach, and how well informed they were about these old, yet new compounds. The EMA's thoughtful feedback and questions, on topics ranging from pre-clinical data to post-regulatory approval scenarios, led us to revise our protocol and clinical development plan and to develop strategies that will ensure our trial demonstrates safety and

efficacy.

Clinical trial programme started

Our clinical trial programme is led by Sue Stansfield, a former global executive at inVentiv Health. Early in her career, Sue completed her PhD focusing on serotonin, and one of her first research projects was conducted in collaboration with Prof David Nutt. We have a strong partner in Worldwide Clinical Trials, our contract research organisation. Worldwide was selected for its commitment to innovation and focus on Central Nervous System (CNS) research. In our first six months of working together, the Worldwide team have demonstrated exceptional engagement, flexibility and resourcefulness. Together we have completed regulatory and ethics submissions in five countries, and have received positive initial feedback from ethics committees and health ministries. We are particularly excited that we have had our first clinical trial approvals, from the UK's Medicines and Healthcare Products Regulatory Authority and the Dutch Ministry of Health. Well done and thank you to everyone involved!

Trial sites selected

In June we began to look for potential trial sites. We were encouraged by the wealth of psilocybin research knowledge that exists in some of the oldest and most established academic institutions in Europe, and among many of the most reputable researchers and clinicians in the field of mood disorders. Twelve sites in the UK, Norway, Finland, the Netherlands, Germany, Portugal, Spain and the Czech Republic have now been selected. We are delighted that Professor Guy Goodwin, former head of Psychiatry at Oxford University and former president of the European College of Neuropsychopharmacology, has agreed to be a coordinating Principal Investigator of our trial. Our COMPASS/Worldwide team has visited all the sites – a definite highlight of the last six months. To all the Principal Investigators and their teams, thank you for your enthusiasm and determination to overcome any and all challenges!

Patient experience at the core of our trial

We have been developing innovative patient preparation and therapist training models, essential components that will help to ensure the safety and success of the study. With considerable input and guidance from Bill Richards, Torsten Passie, Peter Gasser, and the excellent team at MAPS (Multidisciplinary Association for Psychedelic Studies), we are finalising the structure of the therapist training process for the first group of European therapists. This will use a web-based training platform, followed by three days of in-person training, and an apprenticeship with experienced psilocybin therapists at three European academic sites. We are fortunate to be working with two technology partners who share our vision. Longboat specialises in digital support for clinical trials, optimizing the flow of information between patents and study teams, and improving patients' experience of research participation. Longboat will be hosting our digital patient preparation platform, showing animations and videos about psilocybin. Another partner, Mindstrong, will be collecting behavioural markers of depressive symptoms via a mobile application, with the ultimate goal of personalised care for depression.

cGMP (Good Manufacturing Practices) psilocybin now available for research

This year, we have completed synthesis, formulation, stability testing, and all pre-clinical tests for psilocybin. Our psilocybin has made the transition from a research chemical to a medicinal product, ready to be approved upon successful completion of phase 2b/3 trials in the EU and US.

The availability of cGMP-grade psilocybin has stimulated a lot of interest in the scientific community. COMPASS will provide psilocybin for investigator-initiated studies in at least nine countries across Europe, North America and Australia for psychiatric and medical indications, as well as experimental studies, free of charge. All participating sites will be contributing to the unified safety database which will help expedite approval and, ultimately, patient access.

Team growth

In addition to Sue Stansfeld, we have been joined by two new colleagues: John Boghossian, who is leading business and partnerships development, and Molly Lennard-Jones, our team coordinator. John graduated from MIT and the Harvard Business School and comes with experience in market access. Molly developed a strong interest in mental health after completing her research thesis on the role of personal narrative in PTSD among Holocaust survivors. Since September we have also been working with Chris Strutt and Tracy Cheung, formerly of GlaxoSmithKline and GE Healthcare respectively, who support us on public affairs and communications. We are fortunate to have such a talented and experienced group of people in the COMPASS team and our rate of progress has increased rapidly since they have been on board.

We have welcomed two new members to our advisory board: Dr Tom Insel, a neuroscientist and former head of the US National Institute of Mental Health; and Dr Paul Summergrad, the head of Psychiatry at Tufts University Medical School and former head of the American Psychiatric Association. We are deeply grateful to all of them and our ‘founding’ advisors – including Prof Sir Alasdair Breckenridge and Dr John Rush – for their continued support, expertise and wisdom.

Lastly, I want to express my thanks to two people without whom COMPASS would still have been a dream: Joe Heinen, our Chief Financial Officer, and Sarah Drummond, who makes all the important conversations and events happen.

Looking ahead

It has been a very busy year and 2018 is set to continue in the same way. A few key events:

With all the positive signals following our regulatory submissions, we are well positioned to enrol our first patient in March 2018. We expect to complete the enrolment for the dose finding phase of the study by the end of 2018.

A study of 50+ healthy volunteers is planned for Q2 2018. This study will explore the safety and effects of psilocybin on cognitive function and emotional processing. It will also begin to collect safety data on the simultaneous administration of psilocybin in groups of 5-10 volunteers. The study will be supported by psychiatrists experienced in group administration of psychedelics as well as by our therapists-in-training. It will be an excellent opportunity to start building a platform for shared knowledge and professional development for mental health professionals interested in the emergent field of psychedelic research and therapy.

A Pre-Investigational New Drug meeting with the FDA (US Food and Drugs Administration) is planned for January 2018. We plan to share the results of the EMA Scientific Advice with FDA and seek approval for the replication of the confirmatory phase of our TRD trial in the US.

We are always on the lookout for talent. With scientific rigour and patient experience at the core of our work, we plan to hire a lead for therapy research and training, early next year.

We continue to be humbled and inspired by the task ahead of us. We are immensely grateful for the enthusiasm and expertise that has been so generously shared by everyone involved. Thank you for all of your support, it has made such a difference to our work and will undoubtedly make a difference in patients' lives.

I wish you the happiest of festive seasons and all the best for the New Year.

Kind regards,

Katya, on behalf of George, Lars and the COMPASS team