NEWS RELEASE

COMPASS Pathways receives FDA Breakthrough Therapy designation for psilocybin therapy for treatment-resistant depression

2018-10-23

For online press release, see: **https://www.prnewswire.com/news-releases/compass-pathways-receives-fda-breakthrough-therapy-designation-for-psilocybin-therapy-for-treatment-resistant-depression-834088100.html**

COMPASS Pathways, a life sciences company dedicated to accelerating patient access to evidence-based innovation in mental health, has received breakthrough therapy designation from the US Food and Drug Administration (FDA) for its psilocybin therapy for treatment-resistant depression.

The FDA designates a drug as a breakthrough therapy if preliminary clinical evidence shows that it may demonstrate substantial improvement over available therapy. Breakthrough therapies are supported by the FDA throughout the clinical development programme to ensure as efficient a process as possible.

Breakthrough therapy designation is a significant milestone for psilocybin therapy and psilocybin research, and a testament to the work done over many years by research teams in the US, the UK and Switzerland. The Heffter Research Institute was the first to fund research in this field, and supported early studies at Johns Hopkins University, New York University, and Harbor-UCLA. In the UK, the Medical Research Council backed the proof-of-concept study of psilocybin for treatment-resistant depression at Imperial College London in 2015. COMPASS Pathways is now running the first large-scale psilocybin therapy clinical trial for treatment-resistant depression, which will take place in Europe and North America over the next year or so.

George Goldsmith, Executive Chairman, COMPASS Pathways, said, “This is great news for patients. We are excited to be taking this work forward with our clinical trial on psilocybin therapy for treatment-resistant depression. The

FDA will be working closely with us to expedite the development process and increase the chances of getting this treatment to people suffering with depression as quickly as possible."

Treatment-resistant depression is a huge unmet need, affecting 100 million people around the world who do not respond to existing treatments. Depression is one of the fastest growing health problems we face today, and the leading cause of ill-health and disability worldwide. The breakthrough therapy designation for psilocybin therapy highlights the importance of supporting early research that can be translated to clinically meaningful outcomes.

Dr Robin Carhart-Harris, Head of the Psychedelic Research Group, Imperial College London, said, "In our 2015 study, we provided psilocybin to 19 patients in a clinical setting, coupled with psychological support, and found promising signals of efficacy and safety as treatment for treatment-resistant depression. The breakthrough therapy designation is a strong endorsement for the potential of psilocybin therapy. We look forward to learning more as further clinical studies are carried out, by our team at Imperial College as well as in COMPASS's multi-centre trial."

Dr David Nichols, Chairman of the Board, Heffter Research Institute, said, "Since its inception in 1993, Heffter has been helping to design, review, and fund the early phase clinical studies on psilocybin at research institutions in the US and Europe. We are delighted that psilocybin is being recognised as a breakthrough therapy and look forward to continuing our work with researchers and partners around the world so that we can alleviate the suffering caused by mental illness."

About COMPASS Pathways
COMPASS Pathways is a life sciences company, founded in 2016 to accelerate patient access to evidence-based innovation in mental health. We are developing psilocybin therapy through a late-stage clinical trial in Europe and North America for patients with treatment-resistant depression. We will improve mental health through the development of new patient care pathways, based on advances in neuroscience, psychotherapy, psychopharmacology, and technology. **www.compasspathways.com**

Enquiries:
Tracy Cheung, **tracy@compasspathways.com** , +44-7966-309-024