VERANOVA®

Psychedelic Therapeutics:

Bridging the Gap Between Potential and Practice

The emergence of novel therapeutics has been one of the most influential drivers in the pharmaceutical industry over the last decade. As global populations live longer, the pharmaceutical and biotech industries have witnessed a greater demand for more patient-centric, complex, and personalized treatments.

One area in particular that has attracted increased interest over the last few years is the potential therapeutic uses of psychedelics.

Lysergic acid diethylamide (more commonly known as LSD) was one of the first modern psychedelics to be discovered by Swiss chemist Albert Hofmann in 1938; however, its effects were not discovered until 1943. This kicked off an era of modern psychedelics in the mid-20th century and resulted in extensive research into them in the 1950s and 1960s. However, in the late 1960s, many countries worldwide began to criminalize psychedelics due to their potential for substance abuse. As such, there has been limited research into their therapeutic potential.

With a more holistic understanding of how psychedelics can be used in a supervised medical setting, scientists are beginning to explore their therapeutic applications again, especially in the treatment of illnesses such as addiction, depression, anxiety and posttraumatic stress disorder (PTSD).

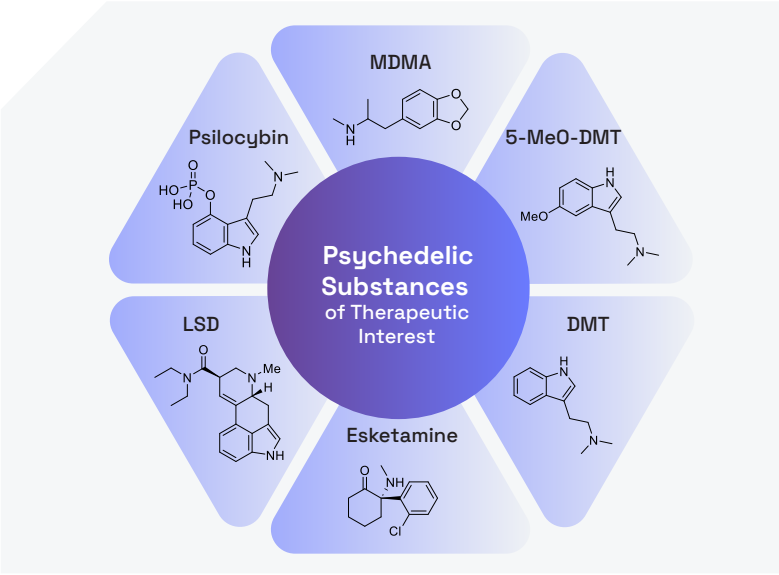

FIGURE 1: Psychedelic substances of therapeutic interest to the pharmaceutical industry

However, there are several challenges associated with the quality, potency, safety, and efficacy of this resurgence in psychedelic substances. As a global CDMO that manages complexity with confidence, Veranova is positioned to help its customers mitigate these project hurdles and ensure consistent product attributes in the development and manufacturing of psychedelic substances for medical applications.

PSYCHEDELIC SUBSTANCES OF INTEREST	POTENTIAL CLINICAL APPLICATIONS
Lysergic Acid Diethylamide (LSD)	Alcohol use disorder, anxiety disorders, depression, Alzheimer's disease
Psilocybin	Several types of depression, smoking cessation, addictive behaviors, pain relief, migraine
3,4-Methylenedioxmethamphetamine (MDMA)	Major depressive disorder (MDD), post-traumatic stress disorder (PTSD), anxiety disorders, eating disorders and other indications
Dimethyltryptamine (DMT)	Major depressive disorder (MDD) and other depression conditions
5-MeO-Dimethyltryptamine (5-MeO-DMT)	Major depressive disorder (MDD) and other depression conditions
Esketamine	Treatment-resistant major depression, pediatric anesthesia, conscious sedation anesthesia, and emergency analgesia

TABLE 1: Potential clinical applications for psychedelic substances

FIGURE 2: The steps of solid form drug development

Complexity with Confidence

Veranova leverages extensive experience in the handling of highly potent active pharmaceutical ingredients (HPAPIs) and controlled substances. We are committed to addressing the challenges that our customers face during the **production, scale up, and process development** of complex ingredients. Utilizing a wide range of services, Veranova can help develop high-quality, safe, and effective psychedelics.

We have expertise in **analytical testing, chemical development, and manufacturing of controlled substances** across our North American and UK sites. This includes the appropriate registrations to handle Schedule 1 substances. Furthermore, Veranova's facilities and resources are well equipped to scale to GMP production of psychedelics for clinical use and meet increasing demands. Most recently, this has included an estimated $30 million expansion at our Devens, MA, site, as well as the completion of increased capabilities at our multi-purpose small and large-scale manufacturing site in Edinburgh, UK.

Regulation

Strict regulatory controls associated with controlled substances may pose a challenge to the continuing research and development of psychedelics. Most psychedelics are classified as Schedule 1 substances in the US and are similarly restricted in other countries. As a result, development and manufacturing activities require government licenses, inspections, and oversight. Veranova has a strong background in navigating regulatory frameworks to mitigate setbacks and efficiently maintain compliance and has extensive experience in the development and commercial manufacture of Schedule 1 drug substance.

Solid Form

In addition, Veranova can further develop the optimal solid form of a target psychedelic molecule through our world-leading solid form and particle engineering capabilities. Under our Pharmorphix® brand, Veranova can investigate the potential for the improved physical performance of an API under study via salt, cocrystal, and polymorphism screening protocols. We assist the selection of a solid form with desirable characteristics such as improved aqueous solubility, increased thermal stability and many other attributes. In conducting such work, we support IP generation and consequently help clients build a strong patent estate for their API. A typical workflow is given above (Figure 2).

Advancing Science with You

Veranova's comprehensive range of services supports your drug development through strict regulation compliance and large-scale production. When conducted up front, solid form studies generate valuable IP and significantly reduce development time and costs. Our expertise and cutting-edge technologies can accelerate the development of psychedelics from drug candidate to commercial product.

ABOUT THE AUTHOR

Dr. Lorrayne Clague is a Senior Scientist, Technical Documentation Specialist at Veranova with extensive experience in pharma. She authors cGMP-compliant documentation and scientific manuscripts. Dr. Clague has expertise in genomic research and technical writing, applying her skills to communicate effectively in the pharmaceutical industry. She has multiple publications in scientific journals from her research at the University of California, Irvine, where she earned her Ph.D. in Biological Sciences. Thanks to Dan Coughlin, Technical Fellow and Craig Grant, VP & General Manager, Cambridge for their technical contributions.

REFERENCES

Tupper, K. W.; Wood, E.; Yensen, R.; Johnson, M. W. Psychedelic Medicine: A Re-Emerging Therapeutic Paradigm. *Canadian Medical Association Journal* **2015**, 187 (14), 1054–1059. https://doi.org/10.1503/cmaj.141124.