8th Annual
Neuropsychiatric Drug Development Summit
Fuelling Next Generation Neuropsychiatric Drug R&D
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EXCLUSIVE INTERVIEW

AN EXCLUSIVE INTERVIEW WITH:

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Building on the momentum from Cobenfy's success, how has the psychiatric drug development landscape evolved over the past 6 to 12 months, and what is the current state of play?

The past 6 to 12 months emphasized that CNS is making a comeback after a long hiatus amongst larger pharmaceutical companies. Companies focused on neurological therapeutics dominated the M&A landscape, and were only second to oncology in overall value. Many of these deals centred around schizophrenia such as Cobenfy and Caplyta (also later for depression) with other psychiatric indications making strides through the approvals of Spravato and Auvelity for depression and Journavx for non-opioid pain treatment.

As to the current state of play, it is important to note that many of these drugs were known, repurposed therapeutics, which means the field in general is playing it safe with compounds that have comprehensive preclinical and potentially clinical data.

- Cobenfy: xanomeline (discovered in the early 1990s but abandoned due to negative GI side effects) combined with trospium (approved in 2004 as Sanctura for urinary incontinence)
- Spravato: enantiomerically purified version of ketamine approved in 1970 for anaesthesia
- Auvelity: dextromethorphan (approved in 1958 as a cough suppressant) combined with bupropion (approved in 1989 as Wellbutrin for MDD)

However, Cobenfy and Journavx represent progress in classic small molecule drug discovery and development by either creating drugs that target a new mechanism of action or performing detailed structure activity relationships to generate high selectivity with limited off-target effects. Despite this success, patients are still in need of unique therapeutics that go beyond incremental improvements that barely outperform placebo. The unfortunate failures of navacaprant and ALTO-100 in MDD reiterate the importance of translatable animal models and biomarkers. I think everyone's eyes are firmly planted on the serotonergic-targeting drugs (especially psychedelics) in clinical trials (i.e. psilocybin, DMT, LSD and new derivatives). Although these also come with limitations, since silver bullets do not exist, this year should provide more clarity on their efficacy and future in psychiatry.

From new targets to emerging technologies, where are the most exciting areas of innovation?

I am personally very excited to see a shift in thinking around single target drug discovery and development for CNS. Anyone working in pharmaceuticals knows how difficult it is to name a CNS medication that only targets one receptor, and most FDA approved medications for neurological conditions were found through phenotypic screening rather than specific target-based interactions. Polypharmacology continues to be an important factor in pharmaceutical research, as well as other complimentary areas like biomarkers, brain imaging, EEG, etc., all of which are gaining momentum that I hope continues. Innovations in the stem cell/

EXCLUSIVE INTERVIEW

organoid space could prove fruitful in aiding our understanding of neuroplasticity and neuroinflammation; however, further clinical validation is needed to prove translatability.

Other areas that may not seem as exciting (but should be considered exciting) are metabolism, bioavailability, and formulations research. All of these are attracting attention as different companies and academic groups discover better ways to enhance blood-brain-barrier permeability, reduce unwanted metabolites, and help increase the bioavailability. Cobenfy, Auvelity, and many CNS candidates currently in development fall within this category.

Which specific challenges are you looking forward to addressing with colleagues at the Neuropsychiatric Drug Development Summit in order to collaboratively propel advancements?

- How to define neuroplasticity and its relevance to specific indications?
- Animal model translatability is a known issue for psychiatry, so what are the validated alternatives?
- Non-Animal Testing Possibilities for IND-Enabling Studies and FDA Approval
- Unique and Novel Biomarkers or Targets for CNS

Which sessions in the agenda are you most looking forward to at the 8th Neuropsychiatric Drug Development Summit?

- Opening Discussion: What Value Do EEG Biomarkers Offer as Translational Tools for Neuropsychiatric Drug Development?
- Rethinking Neuropsychiatry: Moving from Symptomatic Frameworks to a Biology-Led Discipline
- Bolstering the Development of Novel Neuroplastogens & Deciphering Their True Classification
- Leveraging in vitro & in vivo Assays to Decipher Neuronal Circuit Complexity & Better Understand New Drug Profiles
- From Genetics to Biomarkers and Therapeutic Hypotheses in Psychiatric Disorders

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