FAQ: Timeline for Ibogaine Approval

What is the FDA process?

- To commercialize a new drug, the Food and Drug Administration requires three 'phases' of testing to demonstrate that a molecule is both safe and effective for the treatment of a specified condition. Drug makers ("sponsors") finance and run trials for which the study design must be pre-approved by the FDA. Upon successful completion of the final phase, the sponsor can submit a New Drug Application to the FDA. If if the FDA approves the application, the sponsor gains the right to market the drug as a treatment for the specified condition.

How long does it usually take, by phase?

- In all, it can take between 5-12 years to complete a drug trial. The timeline to drug approval can vary significantly depending on the type of treatment, according to a report from Health and Human Services (HHS). Initial discovery of a molecule and treatment in animals may take an indeterminate amount of time, but a molecule cannot enter trials in human beings until a sponsor has submitted an Investigational New Drug application to the FDA.
- **Phase 1** is the first stage in which an investigational drug is permitted to be administered to a healthy sample of human beings, to determine proper dosing and potential toxicity levels and averages **1.8 years.**
- **Phase 2**, which includes placebo-controlled randomized trials in a small sample of human beings suffering from the specified condition, takes about **2.1 years.**
- **Phase 3** requires a drug to demonstrate effectiveness statistically greater than a placebo in two large-scale, well-designed clinical trials. The statistical significance thresholds often require a trial to include thousands of participants in each Phase 3 trial and to include double-blind control groups that receive a placebo. This phase frequently takes up to **4 years.**

How is drug approval accelerated with a 'Breakthrough' designation?

- The FDA can award a "Breakthrough" designation for drugs that demonstrate exceptional preliminary results. The designation grants the sponsor a more efficient process that includes ongoing agency collaboration on trial design, "rolling" review of trial evidence in lieu of compiling years' worth of evidence into a completed application, and priority review of a New Drug Application. These changes drastically reduce costs and uncertainty facing drug sponsors and can facilitate capital formation by the sponsor. One study found that a breakthrough designation can shorten the average time to approval to five years.

Have psychedelic drugs received Breakthrough status?

- Since 2017, a number of psychedelic drugs, including synthetic versions of MDMA ("ecstasy"), psilocybin ("magic mushrooms"), and lysergic acid diethylamide (LSD) have been granted breakthrough status by the FDA. Psychedelic drugs have a pattern of showing strong preliminary results in treating mental health issues.
- Non-FDA supervised clinical trials using ibogaine in foreign jurisdictions have also shown very strong results. If a drug sponsor used the same formulation of ibogaine used in these early clinical trials, it could argue that data already exists to show ibogaine offers a substantial improvement over existing therapies.

Are any manufacturers taking ibogaine-like drugs through the FDA process?

- Yes. Manufacturers Atai's and DemRX's ibogaine-like drug have already completed Phase I and may soon move on to Phase II. Another manufacturer, Gilgamesh, was awarded a $14 million grant from the National Institutes of Health to finance Phase I trials of its compound for the treatment of opioid disorder. State participation in an ibogaine research collaborative could steer funding toward a new drug or potentially support an existing clinical trial.