# A CLINICAL RESEARCH STUDY FOR ADULTS WITH SCHIZOPHRENIA, SCHIZOPHRENIFORM, OR BIPOLAR I DISORDER.

## PURPOSE.

To evaluate weight gain in adults with schizophrenia, schizophreniform, or bipolar I disorder who take a fixed-dose combination of olanzapine and samidorphan compared to olanzapine.

## DESIGN.

This is a Phase 3, multicenter, randomized, double-blind study in adults with schizophrenia, schizophreniform, or bipolar I disorder who are early in their illness.

## SCOPE AND DURATION.

The total duration of this study for a subject is approximately 20 weeks, including a 4-week screening period, a 12-week treatment period, and a 4-week follow-up period.

Subjects completing this study will be eligible to enrol in a long-term safety study (ALK3831-A308). Subjects not continuing in the long-term safety study or subjects prematurely discontinuing from the study will enter the 4-week safety follow-up period.

## MAIN INCLUSION CRITERIA.

Each subject must meet all of the following inclusion criteria, as well as others specified in the protocol, to be qualified to participate in this study.*

- Men and women ages 16–40
- Subject has a BMI < 30.0 kg/m$^2$ at Screening
- *DSM-5* diagnosis of schizophrenia, schizophreniform, or bipolar I disorder who meet criteria for symptom stability
- Meets the following antipsychotic treatment and duration-of-illness eligibility requirements:
  - Subject has had less than 16 weeks of previous treatment with antipsychotics (cumulative; lifetime)
  - Subject has had less than 4 years elapse since the initial onset of active phase of symptoms
  - For subjects currently taking antipsychotic medication, the subject and the treating physician feel that a switch in medication is needed (i.e., unsatisfactory clinical response, AEs, or nonadherence to current medication)

## THANK YOU.

We appreciate your interest in the Enlighten-Early Study. If you know someone who may be eligible, please refer him or her to the participating doctor listed below.

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*Other inclusion and exclusion criteria apply.