



QuetiaFlex QD

Breakable Once-Daily Quetiapine

The company:

Altus is a pharmaceutical company co-developing Value Added Medicines with our partners, each backed by Altus' robust patent portfolio.

Our cost effective products address unmet needs in the growing Pain, Depression, Epilepsy and Anti-schotic markets.

The molecule:

Quetiapine (Seroquel) is a well-tolerated highly effective second generation anti-psychotic drug (SGA) indicated for schizophrenia, manic and depressive bipolar disorder, and major depressive disorder (MDD); Quetiapine may also provide benefit for insomnia, general anxiety, PTSD, OCD and substance dependence disorder. Quetiapine lacks the metabolic and extrapyramidal side effects of some SGA.

The unmet need:

Quetiapine is indicated for a range of indications where patients' needs vary. Adolescents, those with bipolar depression and those with MDD must be titrated to effect. Starting doses are low, target doses are high (400mg-800mg) and titration periods are short requiring multiple strengths to be prescribed to a poorly compliant population. Simplified, yet novel dosing options are required to serve these patients better and find the right dose for them. Immediate release (IR) and extended release (XR) tablets are currently available in a large number of strengths.

The product:

QuetiaFlex tablets are breakable once daily formulations offering simple titration to maintenance levels from a single prescription, dosing flexibility for special populations and dose adjustments for those established on the treatment.

THE OPPORTUNITY

Global sales of anti-psychotic drugs are set to reach \$30Bn by 2030 at a 6% CAGR. While long acting injectable drugs dominate the market, over 80% of patients rely on tablets to manage their disease. When Quetiapine is the right choice, only tablets are available. Quetiapine sales in the 5 major markets reached over \$1.4Bn in 2022 and have remained steady in the face of newer alternatives. New treatment options that serve multiple conditions - cost-effectively - can command significant market share.

Flexible and once-daily dosing to simplify prescribing and improve the lives of many patients.

Today's Products

- IR Tablets:** 6 different strengths (25mg- 400mg) means 6 different prescriptions. Predominantly given at low doses (50-100mg) for hypnotic and sedating effects (no titration). Higher strengths redundant.
- XR Tablets :** 5 different strengths (50mg -400mg) mainly used at high doses (400-800mg) for schizophrenia serotonin and dopamine effects (titration required). Lower strengths redundant
- Both IR and QD Tablets** are used for mood disorders.

Tomorrow's Product

Breakable QuetiaFlex QD Tablets: 3 flexible strength tablets provide multiple low doses, simple rapid titration and flexible, high-dose adjustments from a minimum number of prescriptions. **One product fits all.**

IR (BID) Strength/ Daily Dose	XR (QD) Strength/ Daily Dose	Replacement QuetiaFlex QD Tablet	Use/Initial Dose & Titration
25mg 50mg 100mg 200mg	50mg, 150mg 200mg	100mg Half Tablet: 50mg Intact Tablet: 100mg One and a Half Tablets: 150mg Two Tablets: 200mg	Sleep, Anxiety (GAD) Sedation, GAD, treatment of substance abuse. MDD, GAD Daily titration to fixed dose for adolescent schizophrenia, GAD, PTSD, Bipolar Disorder (Depressive Episodes)
300mg	300mg	300mg Half Tablet: 150mg Intact Tablet: 300mg One and a Half Tablets: 450mg Two Tablets: 600mg	MDD MDD, Bipolar I Disorder Bipolar Disorder, Depressive Episodes - Adults Bipolar I Disorder manic or mixed; acute monotherapy or adjunct to lithium or divalproex - Adults
200mg 300mg 400mg	200mg 300mg 400mg	400mg Half Tablet: 200mg Intact Tablet: 400mg One and a Half Tablets: 600mg Two Tablets: 800mg	Titration dose adolescent schizophrenia. Maintenance dose adult schizophrenia, bipolar disorder 1. Dose adjustments between 400mg and 800mg for schizophrenia, Bipolar I Disorder , dose reductions (elderly)

QuetiaFlex QD tablets employ commercially-proven Flexitab breakable tablet technology backed by robust long life (>15yrs) patents.

PARTNERING WITH ALTUS

Altus is seeking co-development partners in N. America, Europe, Latin America and APAC to bring QuetiaFlex QD tablets to the Market.

In return for a shared portion of the development costs, each co-development partner will receive exclusive commercial rights for their territory. Risk and costs are shared but not sales revenues.

Manufacture by Partner or supply of finished goods both possible.

Co-Development Licensees responsible for Registration in their respective territory.

Approval on the basis of pharmacokinetics studies only for cost-effective commercialization.

For more information contact:
bhickey @altusdrugdevelopment.com