



DeslaFlex XR

Breakable Once-Daily Desvenlafaxine Tablets

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 Antipsychotic markets.

The molecule:

Desvenlafaxine (DVF:Pristiq) is a serotonin/noradrenaline re-uptake inhibitor (SNRI) for the treatment of MDD*. The recommended dose in the USA is 50mg/day where no noradrenaline re-uptake inhibition (NARI) takes place. DVF works only as SSRI at this dose and 50% of its benefit is lost.

The opportunity:

DVF is the pharmacologically equivalent metabolite of venlafaxine (VF). While more variable in effect than DVF, VF is indicated for MDD, GAD, SAD and PD* at doses up to 225mg/day where NARI effects occur. To reach this higher dose, Effexor is supplied in 5 different strengths allowing the flexible titration that avoids intolerable side-effects.

A formulation of DVF that provides the multiple strengths of Effexor for titration, in a cost-effective, simple to use manner, will permit NAR-inhibiting doses to be reached to improve efficacy, while enabling well-tolerated treatment of a wide range of indications including neuropathic pain (inc. DPN*) and other hard-to-treat conditions (e.g. migraine and hot flashes).

The product:

DeslaFlex XR tablets are breakable once-daily formulations of desvenlafaxine available in 50mg, 100mg and 200mg strengths. Breaking DeslaFlex tablets generates 8 different doses for up/down titration allowing the full value of this SNRI to be realized. DeslaFlex XR tablets are backed by patents expiring in 2038.

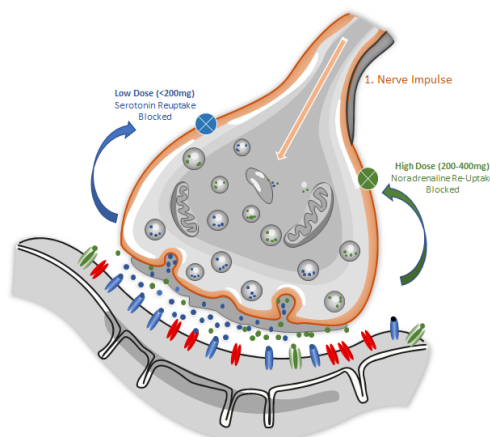
THE OPPORTUNITY

The global market for antidepressants is expected to reach \$24Bn by 2030 at a CAGR of ca. 3%. Once-daily tablets command a significant premium over immediate release forms.

Global sales of Desvenlafaxine grew 11% from 2021 to 2022.

Breakable DeslaFlex XR tablets get the most from Desvenlafaxine

- Desvenlafaxine is a dual mechanism antidepressant with serotonin and noradrenaline enhancing properties.
- Desvenlafaxine remains a highly valuable drug but today's products constrain its utility and limit its efficacy.
- Altus' DeslaFlex XR tablets are convenient to use once-daily formulations of desvenlafaxine in 50mg, 100mg and 200mg strengths. The unique ability to break DeslaFlex XR tablets generates 8 dose proportional dosage strengths that;
 - Allow easy well tolerated titration to doses where NARI occurs and potency increases potential for improved treatment outcomes
 - Allow patient specific dosing - patients receive only the dose they need and no more
 - Broaden product utility for wider therapeutic use.



Desvenlafaxine increases brain serotonin and noradrenaline by blocking their reuptake into cells. Noradrenaline re-uptake only occurs at high doses that cannot be achieved tolerably with existing products

Tablet Strength	Available Doses				Potential Utility
	½ tablet	1 tablet	1 ½ tablets	2 tablets	
50mg	25mg	50mg	75mg	100mg	Starting dose, titration and tapering MDD. SAD. Low body weight and paediatric patients (ADHD),
100mg	50mg	100	150	200mg	Titration in MDD, NPP, hot flushes, dose adjustments for special populations
200mg	100mg	200mg	300mg	400mg	MDD, NPP inc. DPN and PHN,

- Breakable DeslaFlex XR tablets offer an improved QoL for more patients.
- Breakable DeslaFlex XR tablets may be approved on the basis of pharmacokinetic studies alone.
- DeslaFlex XR tablets employ Flexitab technology with patents expiring in 2038

PARTNERING WITH ALTUS

Altus is seeking regional co-development and licensing partners with strong CNS experience to register and commercialize DeslaFlex XR in their territory.

Deal terms include licensing fees in return for regional exclusivity along with success milestones and royalty payments (or equivalent).

Finished good supply or technology transfer models considered.