INVION

Targeting inflammation

INV104 (zafirlukast)

Target: a novel inhaled non-steroidal anti-inflammatory treatment for asthma

Target: an inhaled reformulation of a successful oral therapeutic for asthma

INV104 (zafirlukast):

- Leukotriene-receptor antagonist (LTRA) or “anti-leukotriene” that reduces inflammation, constriction of the airways, and the build-up of mucus in the lungs
- Approved worldwide as an oral tablet for asthma (AstraZeneca)
- Well established clinical efficacy & safety profile
- Inhaled proof of concept using propellants that are now banned (CFCs)
- Inhaled formulation indicated as monotherapy for mild persistent asthma and exercise-induced asthma
- Indicated to reduce inhaled corticosteroid (ICS) dependency in adults and children
  - as an alternative as first controller medication in mild persistent and moderate asthma
  - by addition to low dose ICS treatment rather than doubling ICS
  - by enabling reduced ICS dose “steroid sparing” in steroid-dependent asthma

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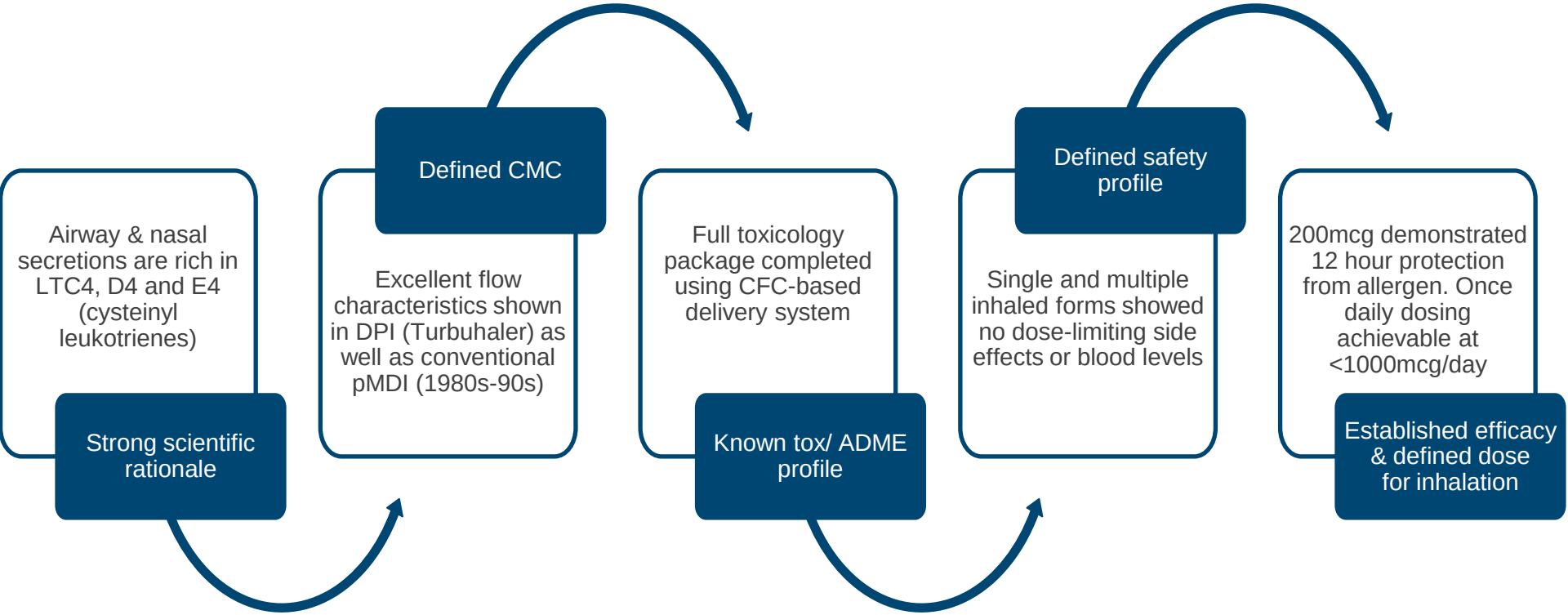
Inhaled zafirlukast an anti-leukotriene: background and rationale



- Zeneca (now A/Z) stopped inhaled development in mid 1990s.
- Zafirlukast and montelukast have resisted formulation in non-cfc propellant systems.

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FDA pre-IND established framework for reformulation of zafirlukast

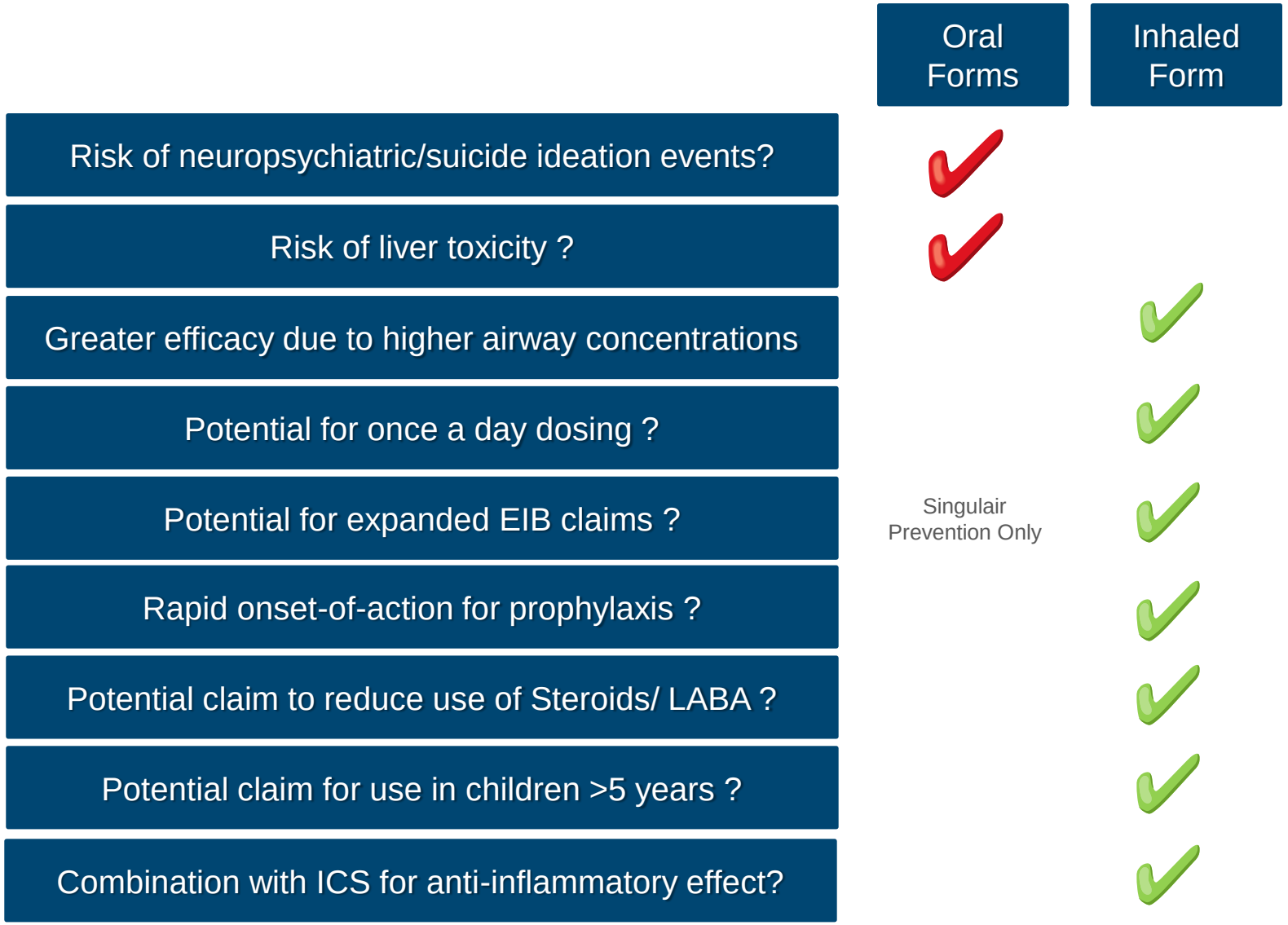
Agreement reached with FDA on:

- chemistry manufacturing and controls (GMP)
  - active pharmaceutical ingredient (API) with drug master file (DMF)
  - formulation: dry powder inhaler (DPI) approved for development

- toxicology and bioanalytical assay (GLP) to support 4 weeks' dosing
  - 2 species for 28 days: naso-pulmonary exposure
  - 1 species for 6 months

- IND submission and clinical program
  - phase I: single rising dose study for safety (paradoxical bronchoconstriction) and pharmacokinetics
  - phase I: multiple dose safety study for safety (paradoxical bronchoconstriction) and pharmacokinetics
  - phase II: challenges to reprise previous studies: cold air, exercise and allergen [cat and ragweed]; steady state dosing for signs and symptoms of asthma [diary card] and attenuation of response to exercise and/or allergen

Inhaled Product Rationale



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Hovione CMC collaboration mitigates major risk of inhaled zafirlukast development

Formulation & device partner, Hovione

- Invion will collaborate with Hovione to develop the proprietary novel technology – a dry powder formulation of zafirlukast and the accompanying inhalational delivery device
- under the terms of the agreement, Hovione will provide chemistry and manufacturing services to develop and optimise the dry powder inhalation formulation which will be delivered using its proprietary device technology known as the XCaps inhaler system
- Hovione device is ideally suited for fixed combination with ICS, bronchodilators, or INV102 (nadolol).
- IP protection provided under licence via Hovione formulation and device, Invion retains commercialisation rights

CMC solution complements existing and planned toxicology and clinical packages

- previously completed using CFC-based device
- Clinical proof of concept based on inhalational challenge studies; previously completed using CFC-based device

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About Hovione and the XCaps inhaler

- International company with over 50 years' experience in the development and compliant manufacture of active pharmaceutical ingredients and drug product intermediates
- With four FDA inspected sites in the U.S., China, Ireland, and Portugal, the company focuses on the most demanding customers, in the most regulated markets
- In the inhalation area, Hovione is the only independent company offering such a broad range of services.

XCaps is a patent protected device filed and granted in over 40 countries, including US (US 8677992) and EU (EP 2546460). XCaps device is simple, reusable and low-cost. This DPI is indicated for applications where a chronic or a medium term acute capsule based delivery of an API is needed.

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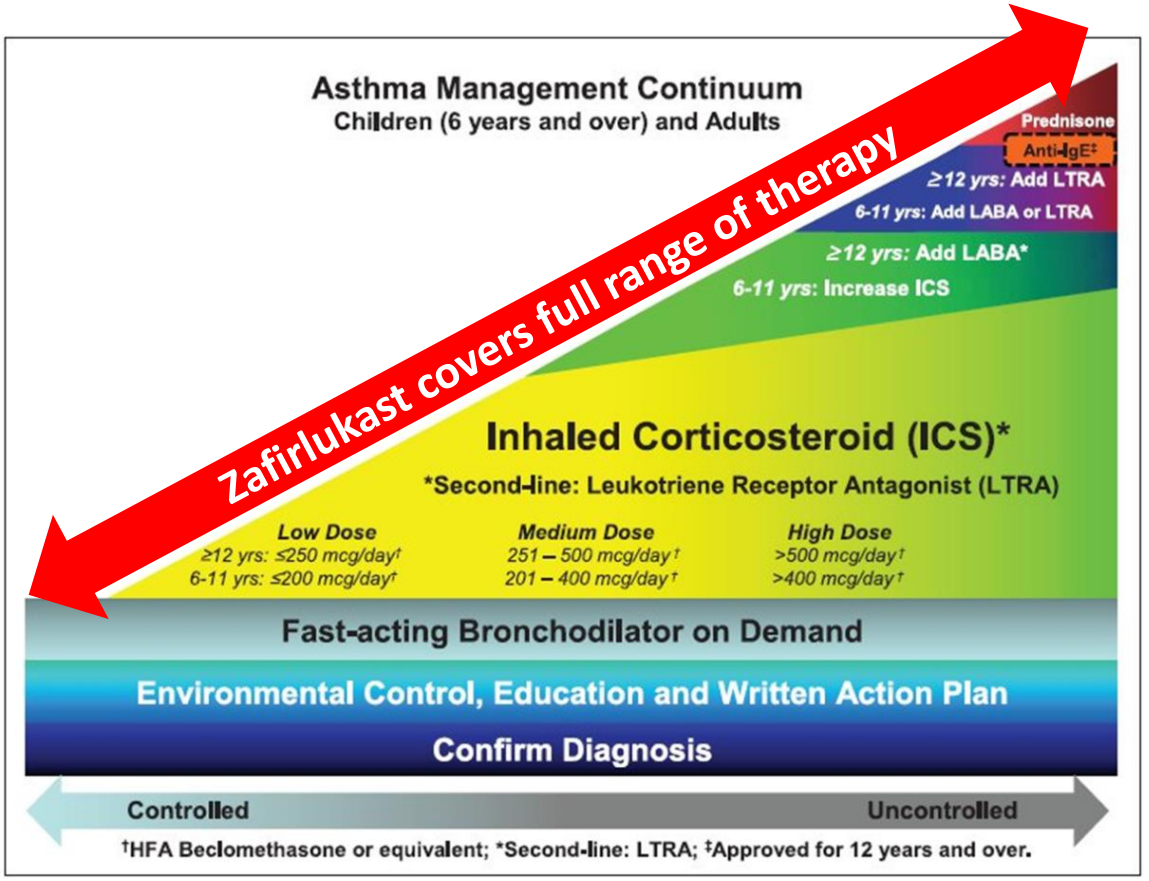
Expected placement of inhaled zafirlukast in treatment regimes

- As many as 334 million people have asthma which occurs in people of all ages. Wheeze is the most common symptom and the burden of disability is high.
- In 2007 the U.S. spent over $56 billion on asthma care, of which nearly $27 billion was spent on pediatric asthma.

Inhaled zafirlukast

- targeted for use as a controller/ preventer with few or no side effects for the full range of asthma therapy
- especially useful in LTD4-driven asthma including aspirin sensitivity and in children
- indicated as steroid sparing
- inhaler will facilitate substitution for inhaled corticosteroids (ICS)
- for many patients, inhaled product alone (monotherapy) will be effective



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Inhaled zafirlukast program: progress and clinical development strategy

Clinical benefits

- ✓ FDA approved as an oral asthma therapy
- ✓ Proof of concept previously conducted using inhaled drug
- ✓ Non-steroidal
- ✓ Higher local concentrations without systemic exposure (decreased risk of generic duplication)

Status of collaboration with Hovione for proprietary formulation and device using Hovione's patented XCaps inhaler system

- ✓ Formulation and device selected
- ✓ Program of works for manufacture of toxicology and clinical supplies
- > Formulation complete for toxicology (non GMP) (3Q2015)
- > Toxicology supplies manufactured (3Q2015)
- > Clinical supplies manufactured to support IND and Phase 1 (4Q2015-1Q2016)

Development program

- ✓ Pre-IND status with FDA
- ✓ Formulation and device collaboration
- > Commencement of toxicology studies (4Q2015)
- > IND submission (1Q2016)
- > Phase I and Phase II clinical studies in (Q1-4 2016)

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