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£4B - Hold that thought!

Say hello to glory days

3 OCTOBER 2023

Hola <<First Name>>,

Inhaled generics: some are good, some are amazing, and some are 💩. We make the amazing ones.

How do we explain inhaled generic failures and foster successes? Over the last 10 years a number of generic companies struggled to develop generic DPI products, a few succeed while others failed. How did it get to that? The connex question is how can this be avoided? Leading to, what budget should you plan to develop a complex generic DPI?, let's say fluticasone/vilanterol/umeclidinium DPI for the US market.

DPIs are the most expensive inhaled generic products to develop and file because they require PK and PD studies and the formulations are difficult to match. Luckily the latest FDA guidances provide some certainty of the tests to perform and possibly an option to use surrogate methods for the PK studies. Great progress has been made on the In Vitro-In Vivo correlations to understand the link between in vitro batch variability and PK responses. If you want to read the latest of this topic, I suggest you read "**Bioequivalence of Two Tiotropium Dry Powder Inhalers and the Utility of Realistic Impactor Testing**", a brilliant study on tiotropium DPI that used MRX003-T10 as the device. It is a good paper to understand what tools can be used to build product specific IV-IV correlations. This should help you stir towards more predictable PK results and avoid the icebergs that others faced.

How much will it cost? Experience indicates that a budget of minimum USD 50 to 100 MM for a complex DPI for the US must be anticipated. At least 1/3 this budget will be for clinical studies, 1/4 of the device (inc. the manufacturing line), 1/4 for the formulation+analytics, and the remainder for other costs. If the same device can be used for other formulations, and for EU products, in the same portfolio (let's say other API combinations), the other products will cost less, possibly a 1/4 less, may be more (1/2?). So which products should you develop? As a rule of thumb, any DPI product that grosses at least USD 100 MM per year is a good target in a specific country or group of countries that share a common approval process. Below that figure, it is necessary to monitor spending carefully or re-use the device and knowledge generated to reduce costs.

There are a few blockbusters left in the inhalation space that are calling for generics, the biggest one will reach £4B revenue by the end of the year. Let's tackle it together, there are still some glory days to be had. Full information on MRX006 is on our website: **www.MRX006.com**.

I will be at CPHI in Barcelona from 24 October if you want to discuss this further.

We also have 2 great downloads on MRX006:

MRX006 DOWNLOADS

We Will Launch You.

This is where you can meet us this autumn term:

- **PODD, Boston, 16-17 October 2023**
- **CPHI, Barcelona, 24-26 October 2023**
- **BioEurope, Munich, 6-8 November 2023**
- **DDL, Edinburgh, 6-8 December 2023**

Below you will find our usual round up of industry and science news about inhaled drug delivery. All published on line on the industry largest OINDP community: **Inhaled Drug Delivery Group**.

I love you
Philippe

🔬 LAST MONTHS TOP SCIENCE BRIEFS

- Quality by design – Spray drying of ciprofloxacin-quercetin fixed-dose combination intended for inhalation
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- Lipid-based particle engineering via spray-drying for targeted delivery of antibiotics to the lung
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- Marketing authorisations for unmet medical needs: A critical appraisal of regulatory pathways in the European Union
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- Inhaled lipid nanocarriers for pulmonary delivery of glucocorticoids: Previous strategies, recent advances and key factors description
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- Preparation and evaluation of sustained release pirfenidone-loaded microsphere dry powder inhalation for treatment of idiopathic pulmonary fibrosis
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- Single-dose pharmacokinetics and lung function of nebulized niclosamide ethanolamine in sheep
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- Theoretical analysis of acoustic and turbulent agglomeration of droplet aerosols
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- Screening of sugars and cyclodextrins as carriers in montelukast dry powder inhalers processed by spray freeze drying
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- Possibilities and advantages of additive manufacturing in dry powder formulations for inhalation
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💼 MARKET CATCH UP

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- Krystal Biotech gets orphan drug designation for KB408 inhaled gene therapy for AAT deficiency
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- United Therapeutics files new suit alleging that Liquidia's Yutrepia treprostinil DPI infringes a patent covering Tyvaso
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- Insmed announces positive topline results from phase 3 arise study of Arikayce® (Amikacin Liposome Inhalation Suspension) in patients with ntm lung disease caused by mac
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- Verona Pharma Announces the US FDA has Accepted the New Drug Application Filing for Ensifentrine for the Maintenance Treatment of COPD
  Learn More
- Lupin pens deal for greater US access to Spiriva generic for COPD Cost Plus Drugs will mail 30-count boxes at $361 each
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- Pulmatrix Announces FDA Acceptance of IND Application for PUR3100 to Treat Acute Migraine
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