



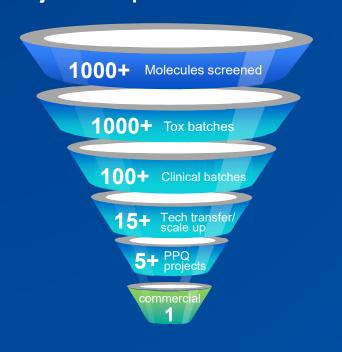




# **Comprehensive SDD Experience and Capability**



#### Projects completed as of H1 2021



## **Shanghai & Changzhou R&D Teams**

Preformulation team: ~ 100 scientists

Formulation & process development: ~ 200 scientists

Analytical: ~ 300 scientists



# **Overall SDD Screening Flowchart**

Characterization
of starting
material

**Screening** 

ASD preparation and characterization

Scale up for PK/Tox study

- Physical property characterization
- Solvent screening
- Surfactant screening
- Polymer screening
- ASD preparation by spray drying
- Physical property characterizations
- In-vitro dissolution
- Short term stability

- SDD scale up (1 lot)
- Physical characterizations
- > In-vitro dissolution
- Suspension feasibility evaluation

- ✓ ~50mg API
- ✓ 1~2d

- √ ~800mg API
- √ ~2w

- √ ~1.5g API
- √ ~2w

- √ ~2g API (TBD)
- √ ~1w

## **Spray Dried Dispersion (SDD) Platform**

- From screening to commercial manufacturing platform
- Plentiful project experience
- PAI and commercial launch experience

### **Clinical and Commercial Stage (GMP)**

Batch Size: 1-10 kg (Clinical) / 10-100 kg (Commercial)

**Preclinical Stage (Non-GMP)** 

Batch Size: 50 mg - 1 kg



**Shanghai**Buchi B90 ↔ ProCepT ↔ Buchi B290 ↔ SD Micro



3-time capacity expansion in 2 years

#### Current

Shanghai / Changzhou

2 PSD-1 spray dryers

2 PSD-3 spray dryers

1 SD-2 spray dryer

# **Expansion in 2 years Taixing**

1 PSD-4 spray dryer (2023)

+ 6 other spray dryers

