



Apinovex™ and Apisolex™ Polymers: New Tools for Solubility and Bioavailability Enhancement

Lubrizol Life Science Health

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Solubility-Enhancing Excipients from Lubrizol

- **Improved solubility and release** for BCS Class II and IV APIs
- **High, stable drug loading**
- **Simple, scalable** formulation techniques
- **Efficient, patient-friendly** dosage forms
- **IP protection** for NCEs and 505(b)(2) products



Why Choose Lubrizol Life Science Health?

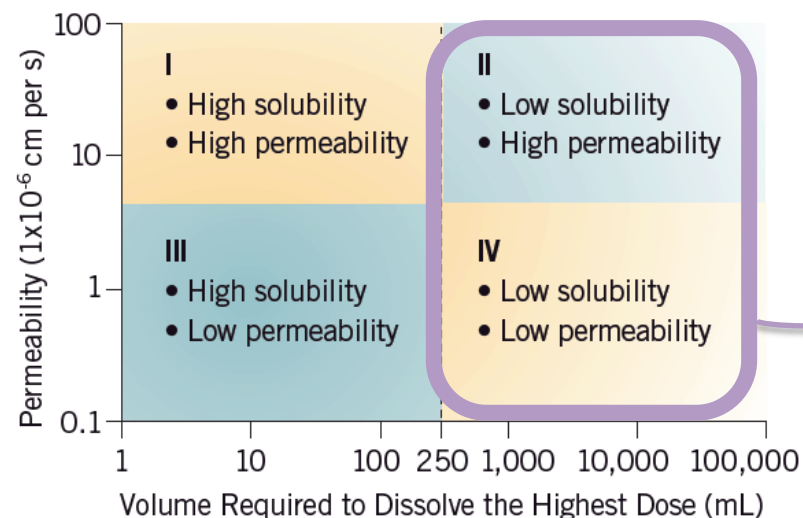
- Safe and effective excipient supply for **over 40 years**
 - Carbopol® polymers
 - Noveon® AA-1 polycarbophil
 - Pemulen™ TR-2 emulsifiers
 - Pathway™ TPU excipients
- Trusted CDMO services for **over 20 years**
 - Decades of collective experience in **nanomilling**

Novel Solubility-Enhancing Polymers



Shortcomings of Traditional Solubility Enhancers

Biopharmaceutical Classification System (BCS)



Up to 90%
of New Drugs

**Low Efficiency/
Poor Dosing**

**Undesired Side
Effects**

**Complex
Manufacturing
Process**

There is no one-size-fits-all excipient!
New tools are needed to serve the growing pipeline of challenging APIs

Key Considerations for Novel Technologies

Formulation Objectives



Patient-Centric Objectives



Business Objectives



Does it Work?

**Is it Safe/
Patient-Friendly?**

**Does it Enable
IP Protection?**

Apinovex™ Polymer for Oral Solubility Enhancement



High molecular weight polyacrylic acid chemistry
designed for spray-dried amorphous solid dispersions

Does it Work?

Enables up to 80%
drug loading

Easy to process via
spray-drying

Is it Patient-Friendly?

Safe for
oral use*

Enables smaller
tablet size

Does it Enable IP?

Patented technology
for ASDs

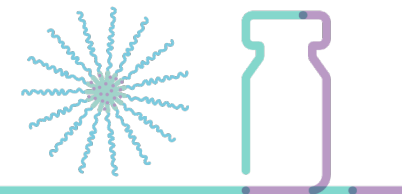
Opportunities for
formulation IP

Apinovex™ Polymers: Looking Forward

- **Samples are readily available**
- Actively **seeking partnerships/ collaborations** with industry and academia
- **New Case Study Data – Q3**
 - Additional APIs with varied physicochemical properties
 - Multimedia and biorelevant dissolution testing
- **Additional Safety/Tox Data – early Q3**
 - Complete histopathology from 28-day study
 - Initiate a chronic *in vivo* study



Apisolex™ Polymer for Injectable Solubility Enhancement



Polyamino acid-based multiblock copolymers
designed for efficient micellar encapsulation

Does it Work?

Enables up to
50,000-fold increase
in solubility
Simple formulation
process

Is it Patient-Friendly?

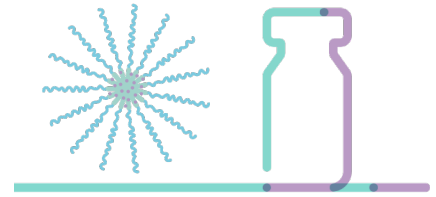
Safe for
parenteral use*
Fast, easy
reconstitution

Does it Enable IP?

Strong composition of
matter patents
Opportunities for
formulation IP

Apisolex™ Polymers: Looking Forward

- Scale up and GMP manufacturing – 3Q23
- Excipient Drug Master File (DMF) – 4Q23
- Safety & Toxicology - Future work to include:
 - Ames
 - in vitro cytogenicity
 - in vivo chromosomal damage
 - Six month repeat dose



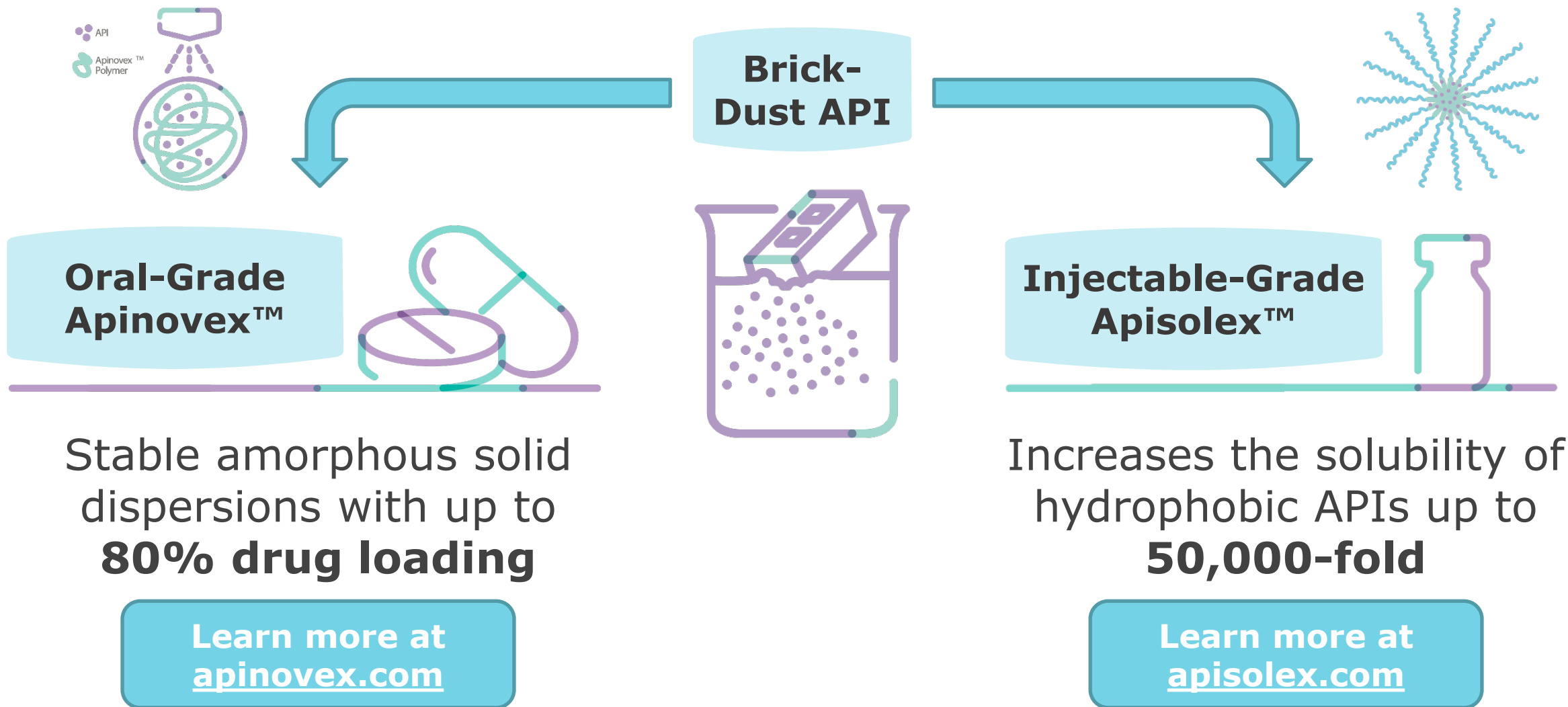
Selecting the Right Partner

The ideal excipient/technology provider will have **deep experience in pharma** and provide:

- **Regulatory Support**
 - Understanding of global requirements
 - Safety/toxicity data for intended purpose
- **Quality and Manufacturing Assurance**
 - GMP manufacturing and documentation
 - Reproducible scale-up capability
 - Stability data
- **A Collaborative Mindset with Secure, Long-Term Supply**



HEALTH Solubility-Enhancing Excipients from LLS Health



Thank you!

Oral-Grade Apinovex™

Nick DiFranco

Global Market Manager

Oral Drug Delivery

Nicholas.DiFranco@lubrizol.com

[Connect with me on LinkedIn!](#)

[Apinovex.com](https://www.apinovex.com)



Injectable-Grade Apisolex™

Joey Glassco

Senior Global Market Manager

Parenteral Drug Delivery

Joey.Glassco@lubrizol.com

[Connect with me on LinkedIn!](#)

[Apisolex.com](https://www.apisolex.com)



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