



www.qprotyn.com

# Qprotyn's Viscosity-Reduction Platform for Monoclonal Antibodies

HILOPRO® Technology
Formulating mAbs for High Concentration – Low Viscosity, SubQ Delivery

# Our Leadership Team



Qprotyn Inc. is a Delaware Corporation founded in 2021 and is an authorized distributor representing BRL.



Lynn Hartung President



Dr. Viren Sarin Chief Science Officer



Janak Vadgama BD & Marketing



Bhami's Research Laboratory is an Indian private limited company (BRL), founded in Mangalore in 2014.



Dr. Bhami Shenoy
Founder &
Chief Scientist



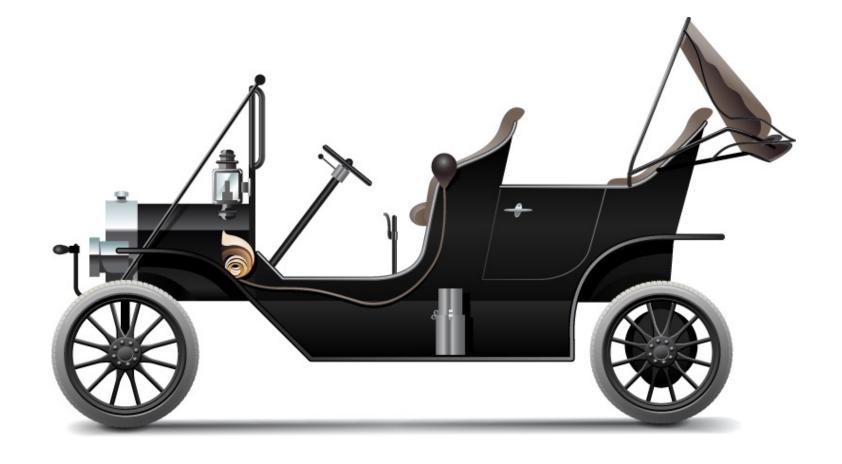
Dr. Surya Pai Co-Founder & CEO

#### Advanced mAbs ...

# ... same old delivery bottlenecks

Inebilizumab Cemiplimab-rwlc **Avelumab** Sacituzumab govitecan-hzly Naxitamab-gqgk Elotuzumab Margetuximab-cmkb Reslizumab Nivolumab Isatuximab-irfc Siltuximab Teprotumumab-trbw Ramucirumab *Ipilimumab* Alemtuzumab **Panitumumab** Cetuximab Palivizumab ...





Basically, even in the year 2024, mAbs can be administered any way you wish, as long as it is IV\*



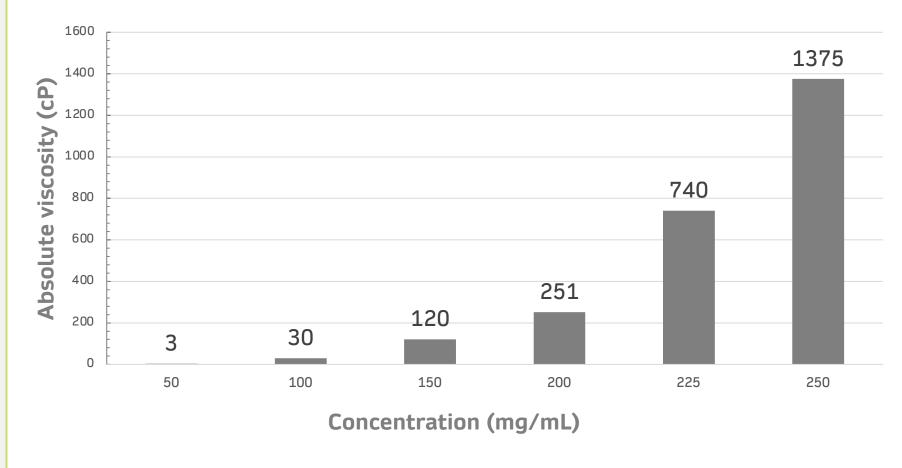
# Physics and Chemistry ... | ... have constrained biologics' delivery

The Constraint?

**High Dose** 

**High Concentration** 

High Viscosity



■ Representative Innovator mAb

Viscosity increases strikingly with higher concentration.



**Qprotyn** represents BRL and is the distributor of BRL's viscosity-reduction technology.

In May 2020, Bhami's Research Laboratory (BRL) was granted a US patent for an elegant new technology that has rewritten this equation:

**High Dose** 

+

**High Concentration** 

+

HILOPRO® Technology

=

**Low Viscosity** 

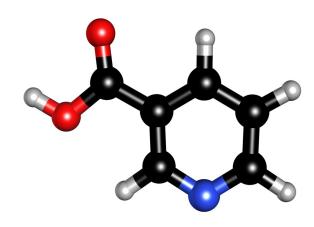


# Safety Data Safety of Excipients

Niacin and Tryptophan used in combination in the HILOPRO® Technology, have a No-observed-adverse-effect level (NOAEL) of 26mg/kg of body weight for Niacin and 15.5mg/kg of body weight for Tryptophan.



Tryptophan



**Niacin** 

These are **GRAS** excipients that have been used independently in commercial parenteral nutritional supplements at high doses.



- Based on a 28-day, repeated dose toxicity study of the excipients conducted at an independent CRO\*
- Additional data and the copy of the complete study can be provided under a CDA

### We're not just saying that...

### ... We can prove it

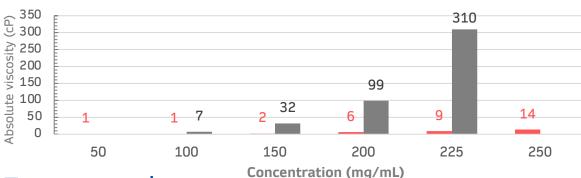
Niacin and Tryptophan have never been used in the in combination for viscosity-reduction purposes.

Together, they show a dramatic reduction in viscosity across all tested mAbs at roughly half of NOAEL values.

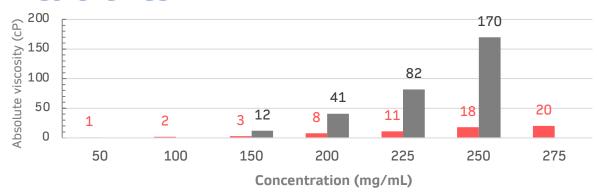
Buffer	Formulation Composition	Protein concentration (mg/ml)	Viscosity (cP at 25°C)
25 mM PHOSPHATE BUFFER, pH = 6.0	HILOPRO® EXCIPIENTS Niacin + Tryptophan	250	18
		264	20
25 mM HISTIDINE BUFFER, pH =6.0	200 mM NaCl and 250 mM Arginine	250	48
	200 mM NaCl	257	59
	250 mM Arginine	264	61
	1737 mM Proline	240	46
	250 mM Thiamine	250	48
	150 mM Nicotinamide	250	51
	690 mM Nicotinic Acid Sodium Salt	226	41
	250 mM Camphor Sulphonic Acid	229	32
	51 mM Caffeine	250	42
25 mM PHOSPHATE BUFFER, pH=6.0	Control: 25 mM Phosphate Buffer Only	250	170
		264	253



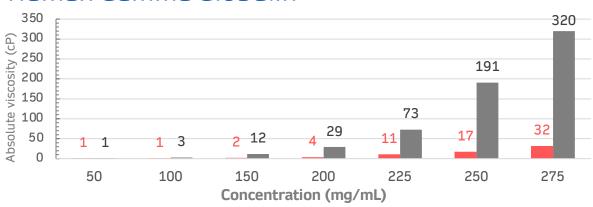
#### Bevacizumab



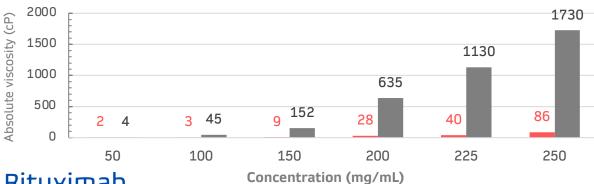
#### Trastuzumab



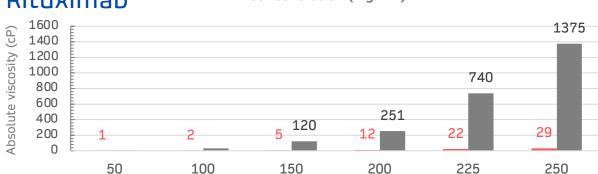
#### Human Gamma Globulin



#### Cetuximab

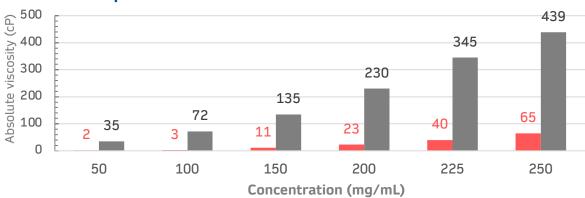


#### Rituximab

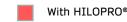


Concentration (mg/mL)

### Etanercept







### It is among the best...

## ... stable, viscosity-reduction platform out there today

In terms of potential, HILOPRO®
surpasses
all contemporary

all contemporary technologies with respect to:

- Universal formulation technology for any mAb
- Platform Application
- Viscosity Reduction
- Cost
- Safety and Stability
- Turnaround time
- Ease of Manufacturing

SubQ Technology	Key Features	Major Disadvantages	
High volume delivery using hyaluronidase	Degrades hyaluronan in the subcutaneous space to allow for high volume delivery	<ul> <li>Long administration time</li> <li>High volume drug delivery</li> <li>High cost of manufacturing</li> <li>Risky self-administration for patients</li> </ul>	
Viscosity reducing excipients and formulation technologies	Use buffering agents and formulation excipients to reduce protein aggregation	<ul> <li>Not suitable as platform technologies</li> <li>Potential safety and toxicity concerns</li> <li>Inferior viscosity reduction abilities compared to HILOPRO®</li> </ul>	
Fluid suspension and crystallization	Use specialized particle engineering, crystallization, atomization or dehydration techniques	<ul> <li>Particles are in suspension formulations, not solutions</li> <li>Not tested successfully for significant number of mAbs</li> <li>High cost of manufacturing and scaling-up</li> </ul>	
High viscosity injection devices	Use high force and resistant containers to deliver high viscosity formulations	<ul> <li>Inherent stability challenges</li> <li>Not tested successfully for significant number of mAbs</li> <li>Increased injection site pain</li> </ul>	



### ... High Concentration + Low Viscosity = Low Volume

### A single formulation

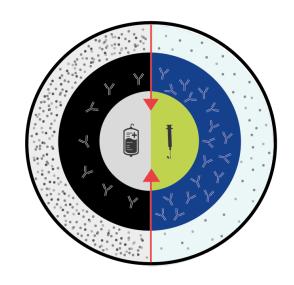
technology that supports multiple dosing and delivery options

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**Greater Flexibility** 

+

Optimal patient convenience



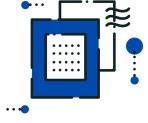
High-concentration, low-viscosity, low-volume dosing opens new delivery possibilities (while retaining existing delivery capabilities).







SubQ



Microneedle Patches



Ocular /
Intravitreal



Wearable Device



# Dose (Fixed or variable) **Formulation** Devices (Concentration (Type of device and viscosity) and volume) Delivery (High concentration -Low volume IV or SubQ)

# IV to SubQ is a System Approach

Example	Current System	HILOPRO® System	
mAb Dose	500mg	500mg	
Concentration	10mg/mL	250 mg/mL	
Form	Lyophilized powder for reconstitution	Solution	
Delivery	IV	SubQ	
Device (Vol.)	Infusion Bag (100mL)	Syringe Autoinjector Wearable Device	
Viscosity	NA	< 20 cP	
Time to administer	30 - 90 min	< 1 min	

✓ Safety

✓ Temperature stability

√ Shelf life

✓ Efficacy

✓ Bioavailability

✓ Patient Convenience



Excipients approved by the US-FDA and used in commercially available parenteral supplements



High concentration, low viscosity >200mg/mL at 18cP



Confirmed stability at 4°C and 25°C under test conditions



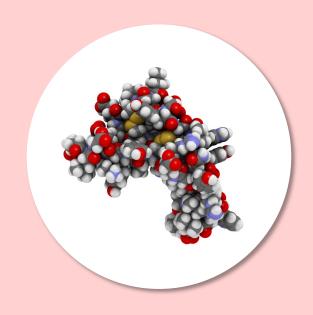
Potential for Longer Lasting efficacy as compared to IV delivery



Administration time reduced from hours to minutes

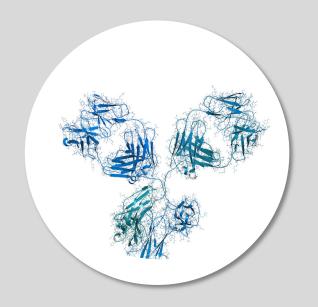


# **Qprotyn Value Proposition**



Innovator mAbs

Dosage of >500mg can be now delivered direct to SubQ instead of IV.



mAbs in Trials

mAbs in trial can be upgraded from IV to SubQ administration.



Bio - betters

First-mover advantage and differentiation value for SubQ biosimilars over dominant innovators.

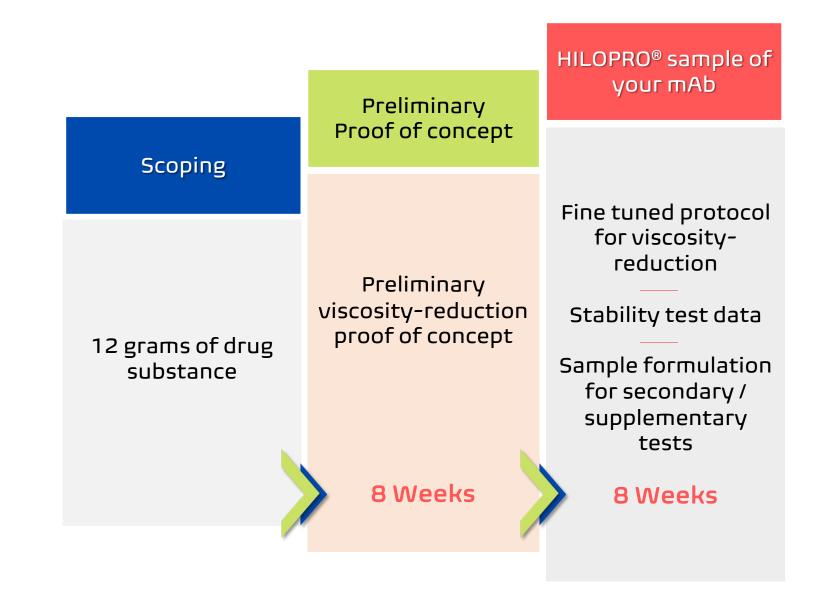


# High dose mAbs and Biosimilars' pipeline

We would love to !!

Proof of Concept in 8 weeks.

HILOPRO® formulated for further testing, in 16 weeks





# Changing the world one mAb at a time.



Email: info@qprotyn.com

Website: www.qprotyn.com

1-844-QPROTYN

1-844-777-6896

125 Cambridge Park Drive, Suite 301 Cambridge, MA 02140 (USA)