

Solv4U

Formulation Development

Solve the un(dis)solvable

2022



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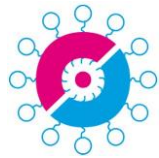
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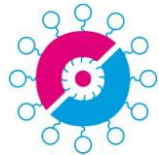


Marinosolv[®], the basis for better therapies

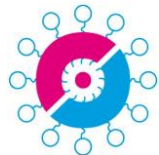
Solubilization technology to improve drug delivery and bioavailability



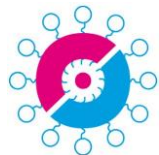
Based on plant derived saponin micelles, proven as clinically safe



Suitable for highly hydrophobic small molecules and peptides



Most advanced asset: Budesolv[®] (budesonide), preparing application



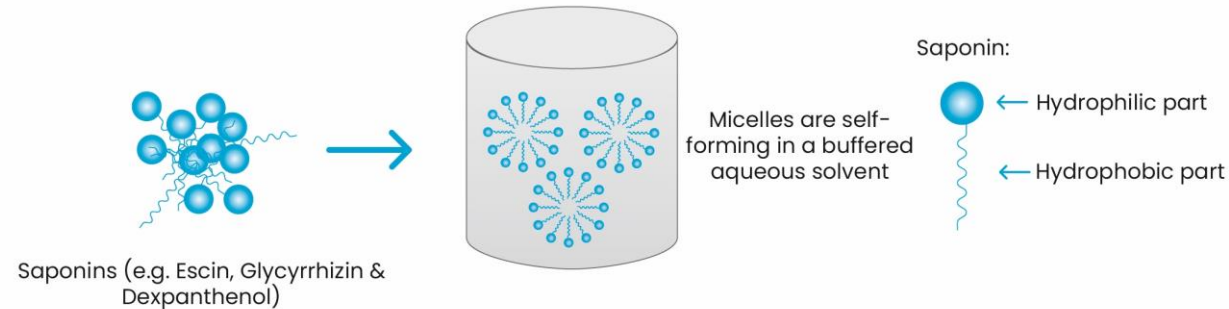
Supported with a strong patent family (novel use), protection until at least 2036



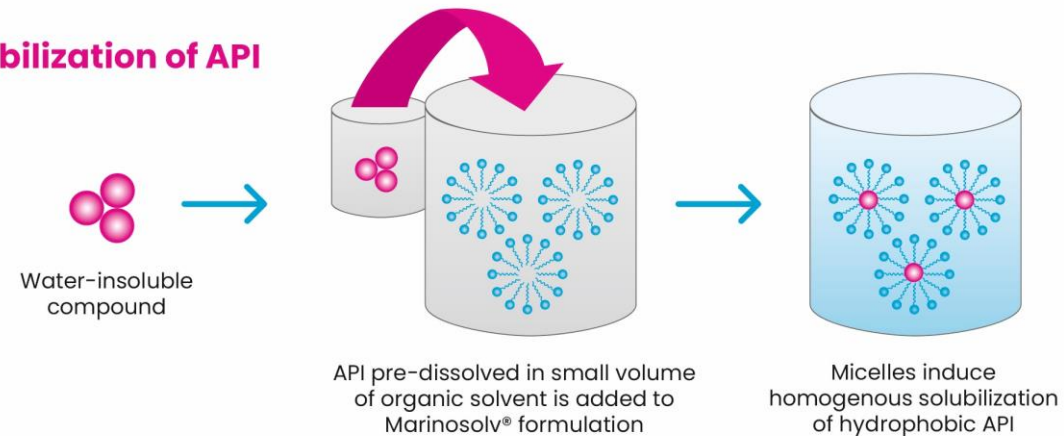
Marinosolv® works in two steps

Solubilization of water-insoluble compounds in a micelle forming aqueous system

Marinosolv® formulation



Solubilization of API

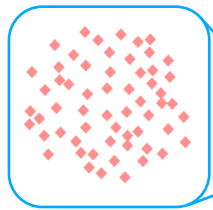


Marinosolv[®] enhances bioavailability

Improved solubility as exemplified on the lead product Budesolv

Suspended particles

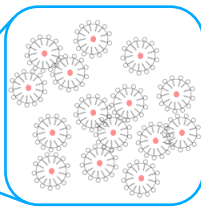
Rhinocort Aqua (J&J)
Budesonide nasal spray



Marinosolv[®]

Stable Micelles

Marinosolv[®] enabled
Budesonide nasal spray



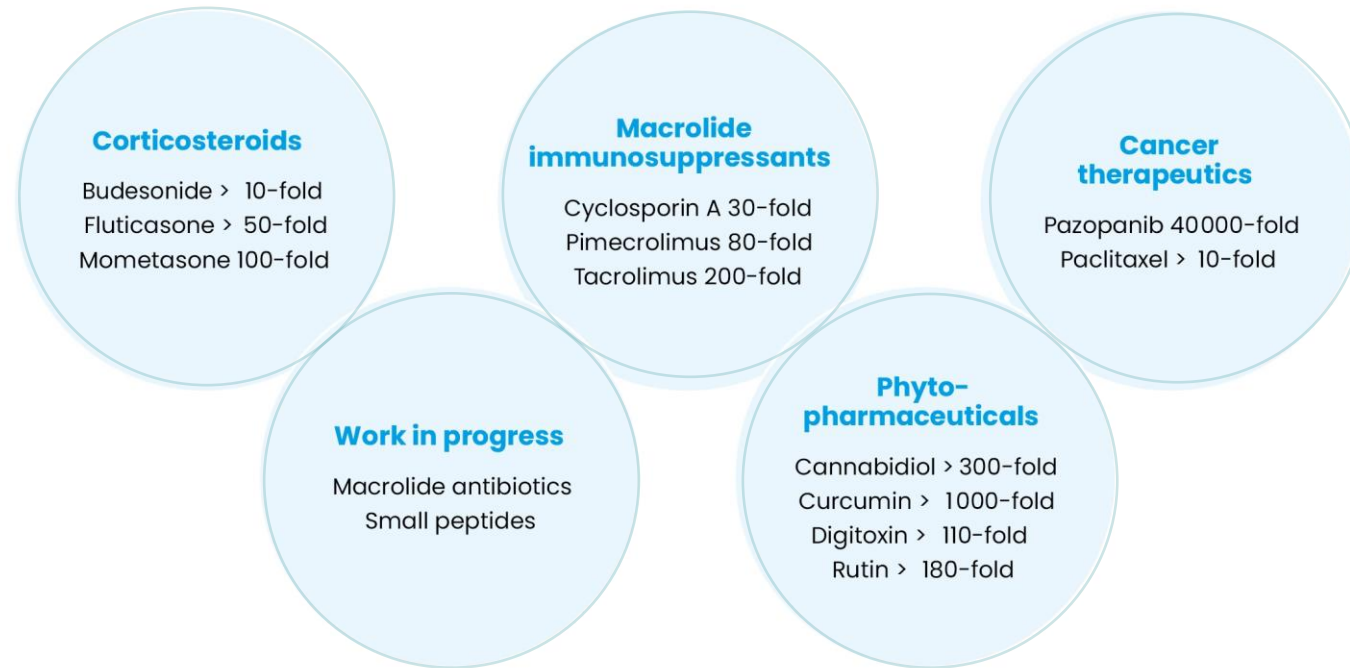
Suspension
64µg per dose/spray

Solution
10µg per dose/spray

Proven solubility	Significant solubility increase in water
Increased bioavailability	Faster onset of action Higher local, lower systemic availability
Well-established excipients	Well-tolerated by sensitive tissues like nasal mucosa and eyes
Dose reduction	Lower possible side effects Lower production costs
Risk of misdosing eliminated	No need to shake the product
Aseptic filtering	Preservative free formulation Lower production costs

Marinosolv[®] enabled compounds

Versatile platform allows solubilization of variety of small molecules

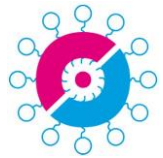


Marinosolv[®] solubility enhancement in comparison to solubility in water.

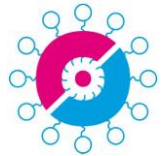


Marinosolv[®] is broadly applicable for NCEs/APIs

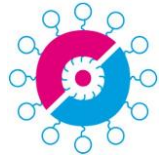
Solv4U technology partnerships in formulation development



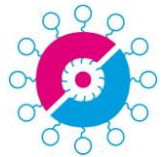
Not limited to APIs for specific indications



For APIs/NCEs in all stages of development



Re-Formulation of off-patent APIs: life cycle management



Efficient drug delivery with low systemic off-target activity



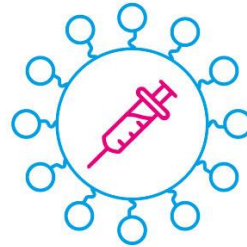
Solv4U, the basis for better therapies

Application and dosage forms

Application routes



Local
(e.g. intranasal/ocular)



Systemic
(e.g. oral/intravenous)

Dosage forms



Solid
(in development)



Liquid solution
Semi-solid



Marinosolv[®] formulation: Local applications

Validation of Marinosolv[®] solubilization technology

BUDESOLV

- Marinosolv[®] enabled budesonide
- Nasal spray
- Phase III (allergic rhinitis) finalised
- Faster onset of action at reduced dose compared to originator
- Licensed to Chinese Partner

TACROSOLV

- Marinosolv[®] enabled tacrolimus
- Eye drops
- Phase II (dose finding) finalised
- Dose dependent effect was shown in allergic conjunctivitis
- Further development in ophthalmic rare diseases



Marinosolv[®] formulations: Systemic applications

Excellent tolerability and efficacy of Marinosolv[®] vehicle

ORAL USE

in pre-clinical toxicological studies

- ✓ Excellent tolerability
- ✓ No clinical signs of toxicity

INTRAVENOUS USE

in pre-clinical toxicological studies

- ✓ Excellent tolerability
- ✓ No clinical signs of toxicity

PHARMACOKINETICS:

in-vivo study of NCE

- ✓ Marinosolv[®] formulation of NCE superior to competitor formulations
- ✓ Per oral: several fold increase in bioavailability compared to competitor

SAFETY & EFFICACY:

in-vivo study of NCE

- ✓ Promising safety profile of Marinosolv[®] vehicle in preliminary PK
- ✓ Marinosolv[®] formulation superior to competitor in bioavailability and general safety

References:

Repeated Dose Toxicity Pilot Study conducted by IOCB (2020) to characterize the toxicity profile of Marinosolv[®] vehicle in Wistar Rats
Pharmacokinetic Study of an NCE in Wistar Rats by IOCB (2021) to determine the pharmacokinetic profile of Marinosolv[®] - enabled NCE



Solv4U: Designed in close cooperation with clients



Formulations are designed according to...

- Physicochemical uniqueness of each compound
- Target stability

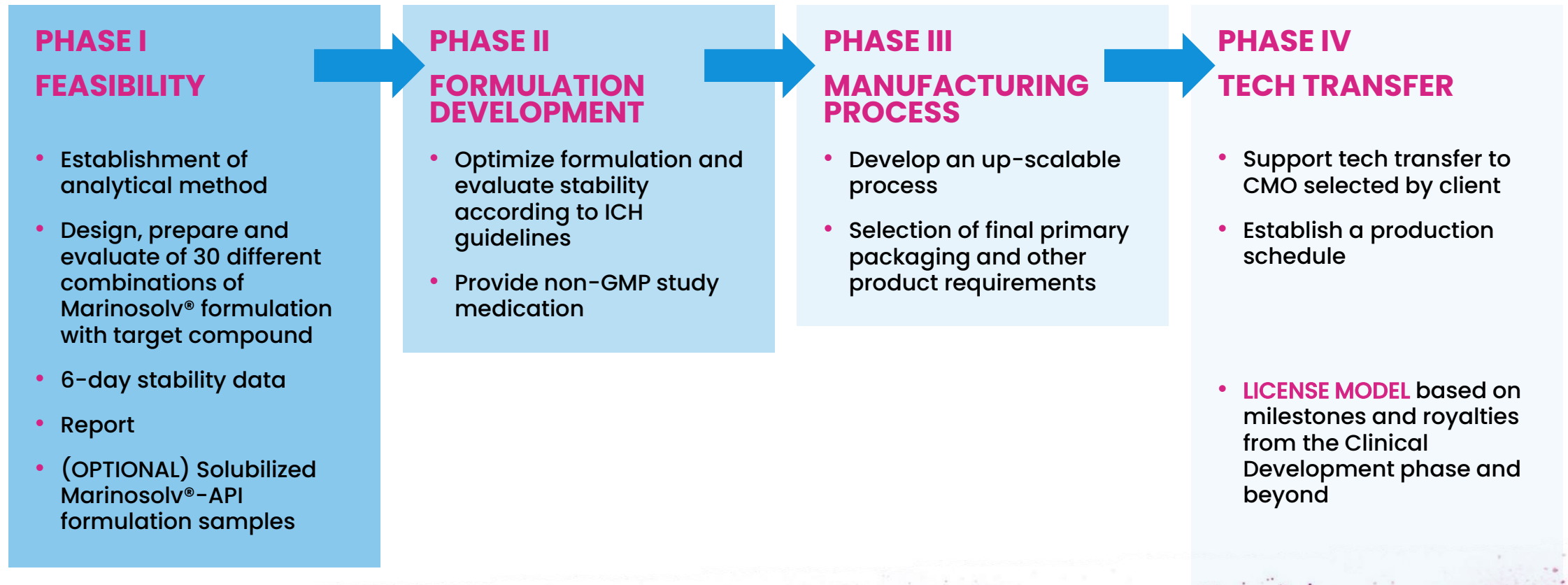
Considering requirements for...

- Later development stages
- Desired dosage forms
- Manufacturing



Solv4U: Formulation development

Feasibility study and development of scalable manufacturing process



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For inquiries reach out to Susanne Bach, PhD

Senior Manager BD & Licensing

susanne.bach@marinomed.com

