Company presentation 22 November 2023
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Xspray Pharma's XS003 Achieves Superior Bioavailability Milestone, Matching TASIGNA® at Reduced Dosage

PRESS RELEASE 2023-11-21

Xspray Pharma's XS003 Achieves Superior Bioavailability Milestone, Matching TASIGNA® at Reduced Dosage.

- XS003, an amorphous non-crystalline nilotinib, designed to overcome therapeutic limitations of the currently available crystalline formulation of nilotinib (TASIGNA®), is the second protein kinase inhibitor (PKI) product candidate developed with Xspray's HyNap™ technology
- TASIGNA is an import treatment for chronic myeloid leukemia (CML), with worldwide sales in 2022 approaching $2.0 billion, despite a labeled warning for food interactions and a boxed warning in the US
- New Drug Application (NDA) is expected to be submitted to the US Food and Drug Administration (FDA) in the second half of 2024.

Executive Summary

Multi-billion-dollar pipeline opportunities with improved PKIs

HyNap™
Scientific Technology Platform

- Paradigm shifting technological breakthrough
  - Alters physicochemical properties
  - Improves pharmacokinetics attributes
- Applicable across PKI molecules – multiple molecules successfully improved
- Defined regulatory pathway under 505(b)(2)
- Lowers R&D spend
- Lowers clinical trial risk
- Lowers commercial risk
- Premium products, with parity pricing

DASYNOC™
The Dasatinib You Know, Now Consistently Delivered

All patients require and deserve consistent delivery of dasatinib to optimize its full clinical potential

- Lead asset on track for FDA approval and commercial launch in September 2024
- Strong patent position
- Premium product profile to reference drug SPRYCEL® (crystalline dasatinib)
- Improved pharmacokinetic precision reducing exposure outliers (high/low) with the potential to improve safety and efficacy
- Excellent prescriber and payor acceptance
- Strong commercial partner
- Commercial platform for additional follow-on products

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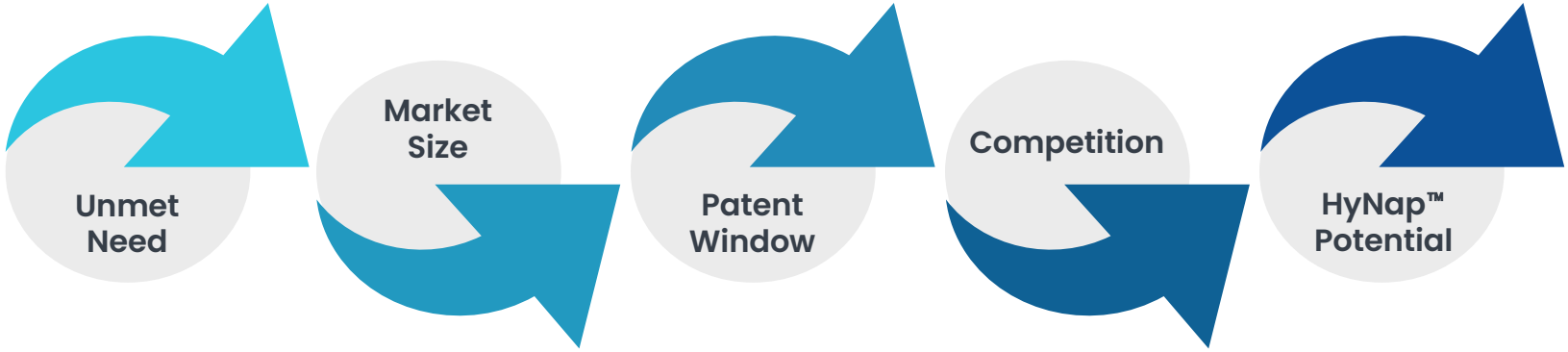
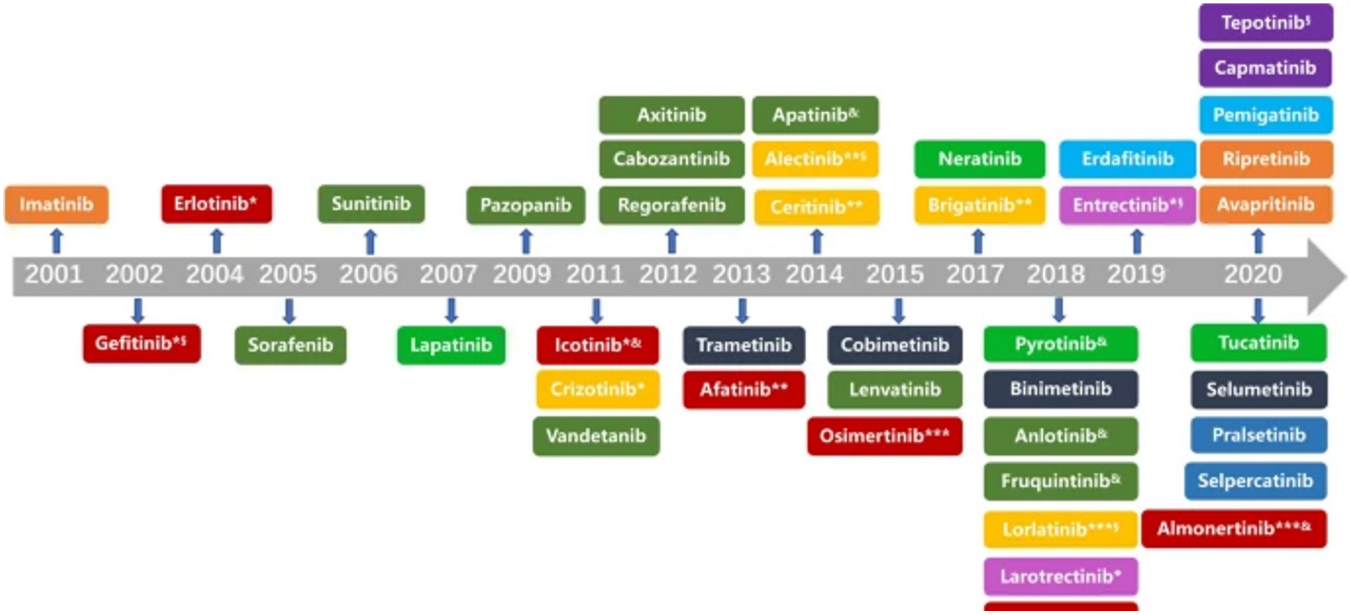
Robust pipeline leveraging unique development platform optimised for launch window timing



Project	Substance	Key Indication	Substance Ip Expiry Date	Secondary Ip Expiry Date	Develop Improved Properties	Test In Man	Pivotal Bioequivalence Study	File To FDA Litigation	FDA Approval End of Litigation	Launch Product	Original Product / Company	Original Product Sales in US
Dasynoc	dasatinib	Leukaemia (CML, ALL)	Dec 2020	Sep 2026							Sprycel / BMS	USD 2.2bn / year
XS003	nilotinib	Leukemia (CML)	Jan 2024	Feb 2032							Tasigna / Novartis	USD 0.9bn / year
XS008	axitinib	Kidney Cancer (RCC)	Apr 2025	Dec 2030							Inlyta / Pfizer	USD 0.6bn / year
XS00Z	Undisclosed											

Protein Kinase Inhibitors:

- Gleevec (imatinib) first PKI approved in 2001
- **Major shift in oncology therapeutics**
- Subsequent explosion in both agents and indications
- Responsible for improving the **10-year CML survival rate from 20% to 80-90%.**



- **84 currently available in the US**
- Require high and consistent oral bioavailability for optimal therapeutic response
- **96% of currently available PKIs are in crystalline form**

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Efficacy and Safety of PKIs Challenged by Drug Delivery

- Chemotherapeutics administered at **intravenous (IV) infusions allows precise control of drug exposure** and plasma levels
  - Requires dedicated infusion centers, personnel, time
- **PKIs cannot be administered IV** as they are insoluble at blood pH
- PKIs must be **administered orally to take advantage of acidic gastric pH** for dissolution and absorption
- PKI **absorption into blood is highly variable**
  - variation in gastric pH
  - presence/absence of food
  - concomitant medications that alter gastric pH

Efficacy and safety of PKIs are highly influenced by variable absorption

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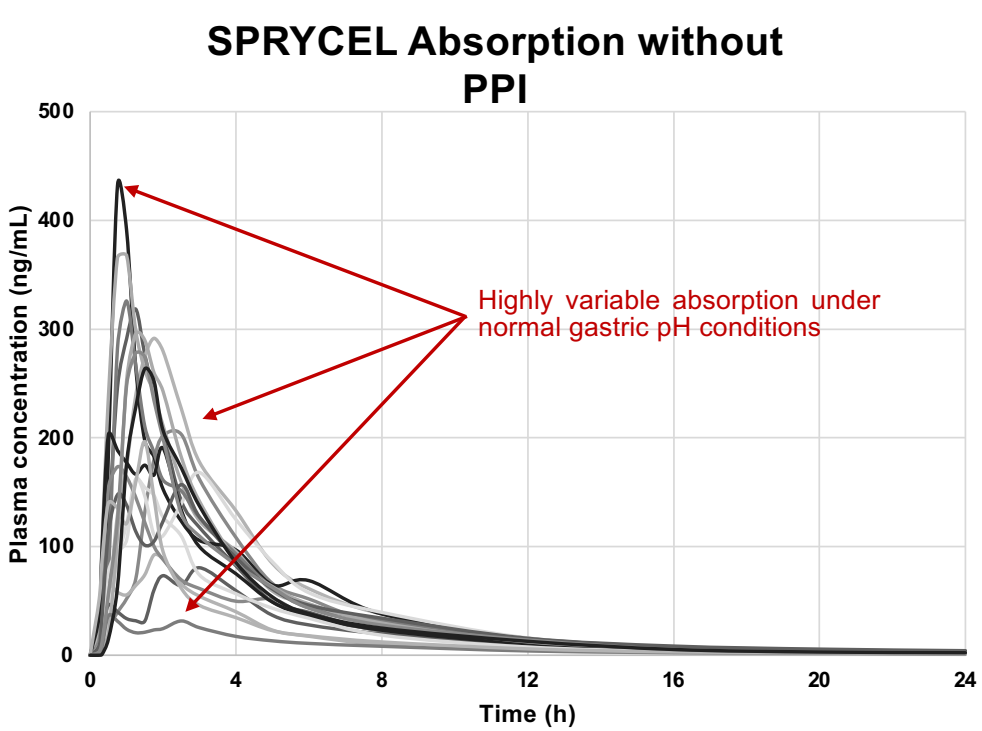
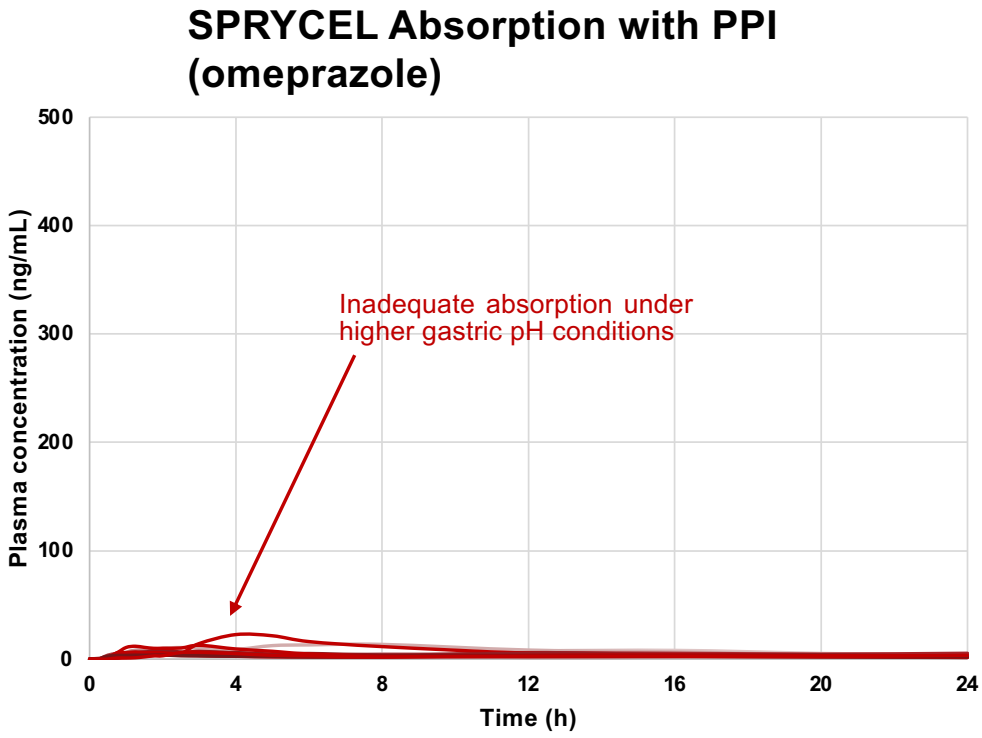
The Problem....Crystalline PKIs Exhibit Highly Variable Absorption Especially in the Presence of High Gastric pH

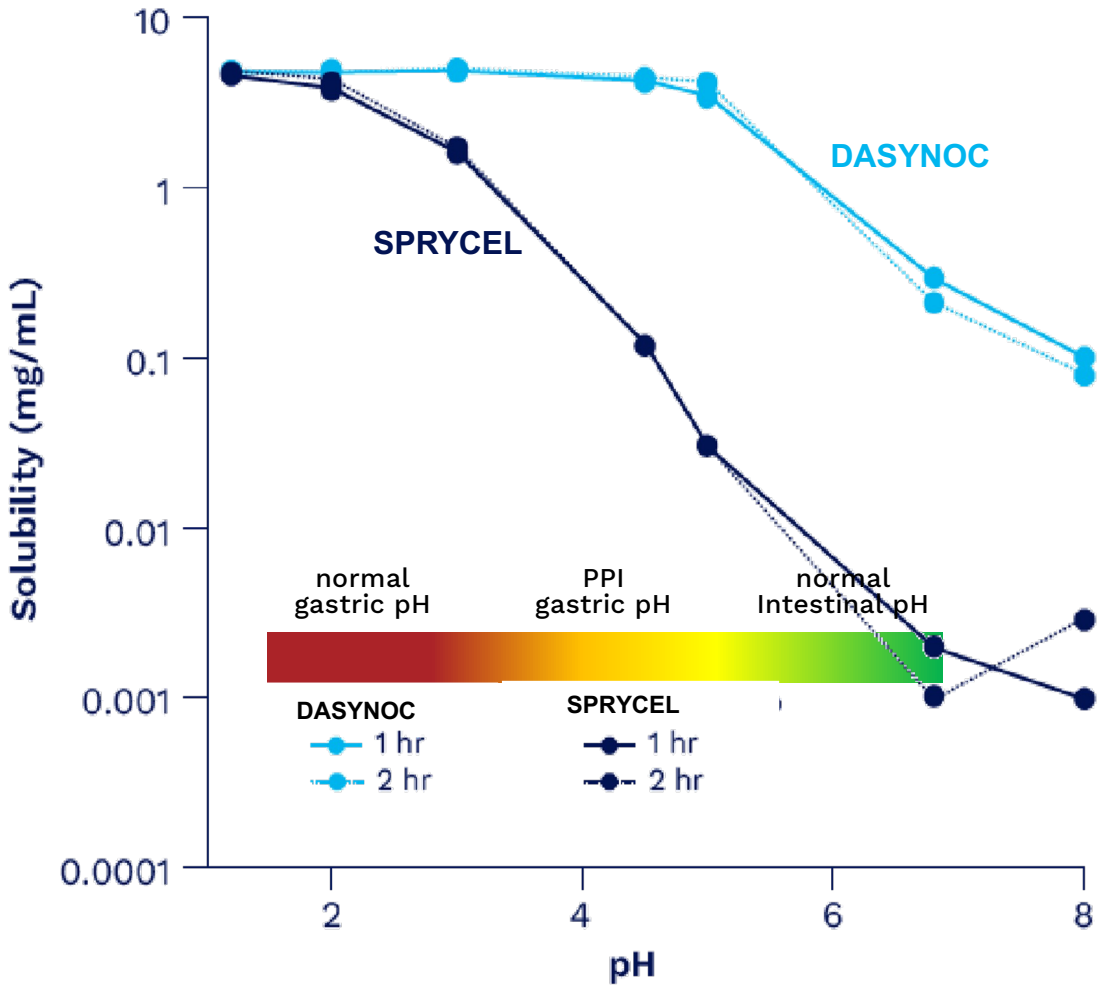
SPRYCEL (crystalline dasatinib) example





Amorphous Formulation of PKI From HyNap™ Overcomes Sensitivity to Gastric pH

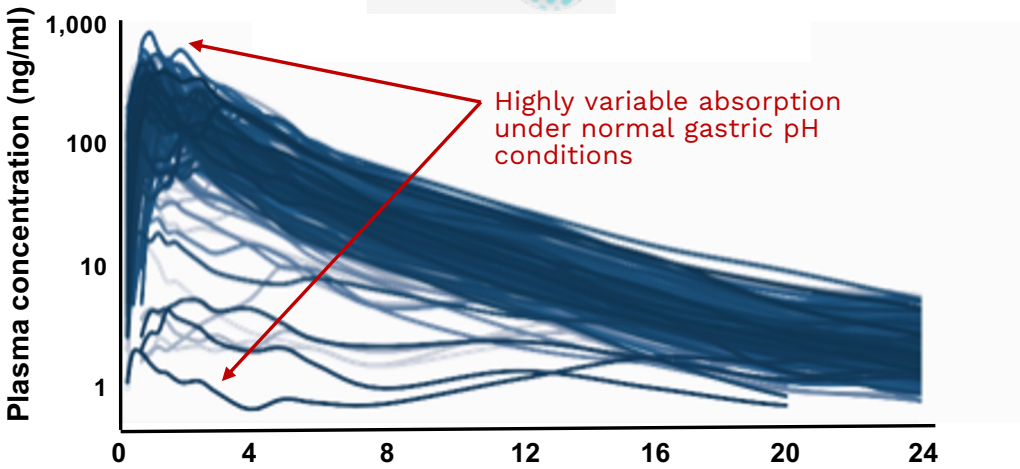
- **Solubility les sensitive to pH**
- **Solubility remains intact far above normal variations in gastric pH**
- **Solubility remains intact despite food-related changes in gastric**



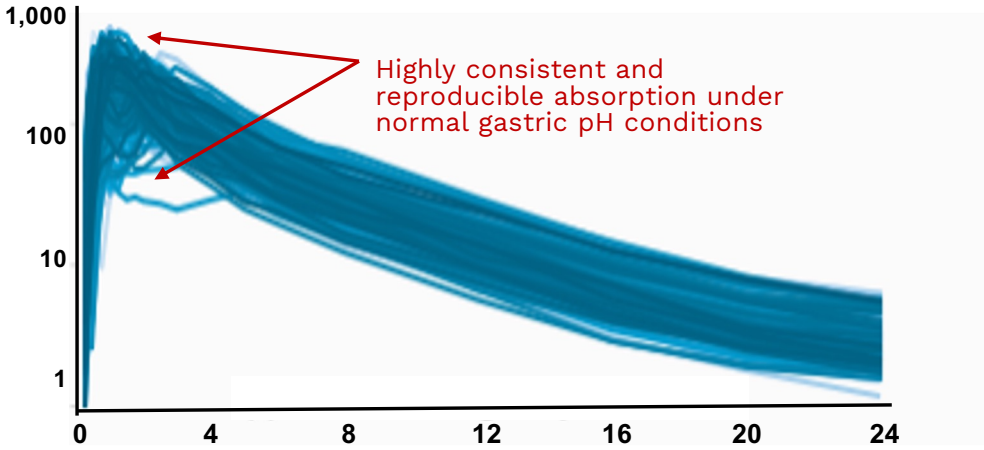
HyNap Technology Offers Pharmacokinetic Advantages

Reduced intersubject and intrasubject variability in drug exposure: Precision Pharmacokinetics

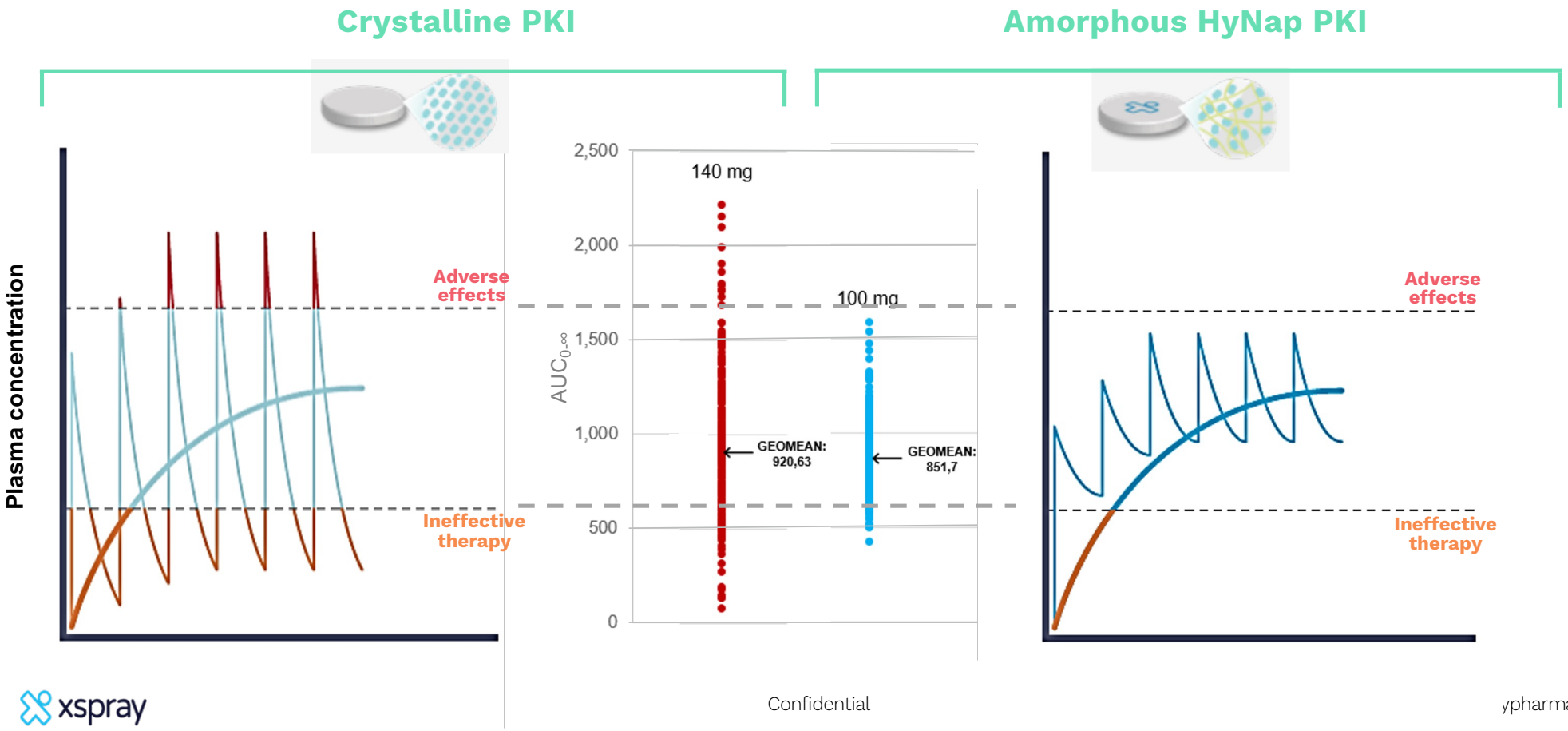
SPRYCEL
(140 mg crystalline dasatinib)



DASYNOC
(100 mg amorphous dasatinib)

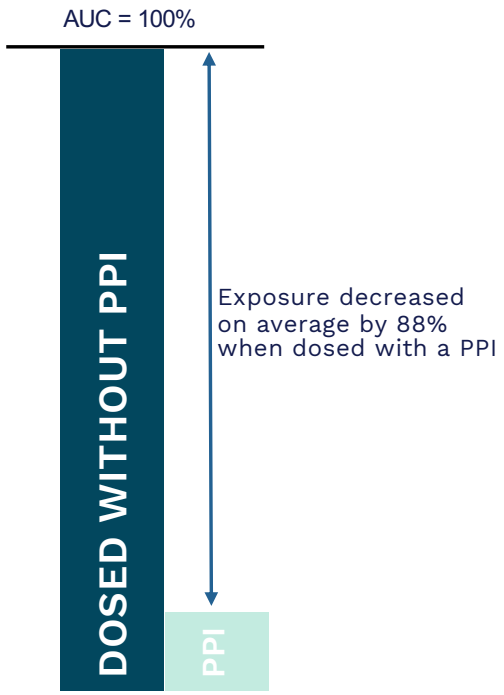


Conceptual Explanation – Amorphous HyNap PKIs Can Operate in the Therapeutic Window with Low Risk of Side Effects



SPRYCEL Drug-Drug Interactions with PPIs Increases Mortality Risk

SPRYCEL absorption significantly reduced by PPIs



SPRYCEL patients commonly co-medicate with PPI

PKI + PPI comedication in CML Patients

Swedish Registry	47% (of 676) **over 5 yr period**
Symphony Data (US open claims)	38% **of dasatinib new starts**

Data does not account for OTC PPI use

SPRYCEL and PPI increases mortality risk

	SPRYCEL	SPRYCEL and PPI
5-year Mortality	6%	21%
Mortality	**3.5: 2.1 - 5.3** P<0.0001	
Adjusted* Mortality	**3.1: 2.1 - 4.7** P<0.0001	
	HR: 95%CI	

[1] Larfors *et al*. Poster, ASH, Dec. 2022

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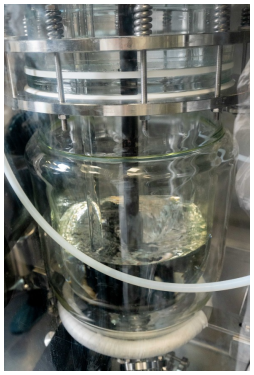
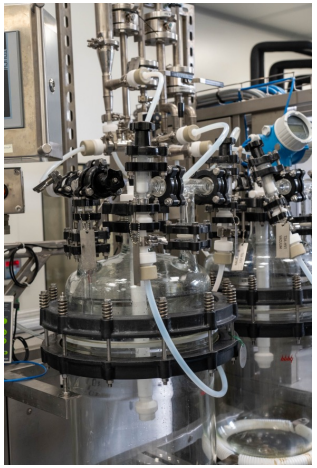
DASYNOC's Precision Pharmacokinetics Maintained with PPI Co-Administration

- ***Solves the drug-drug interaction*** with SPRYCEL and PPI
  - Reduced risk of subtherapeutic levels
  - Enables coadministration with this very common drug class
- ***"Low hanging fruit"*** in which approximately 50% of patients are co-prescribed PPIs

HyNap™ Technology Platform: Scalable and Market Ready





Two production lines (Italy, Nerpharma)

- **Both units inspected by the FDA in Q1 2023**
- **Approved for production of commercial material by Italian authorities (AIFA)**

DASYNOC in CML and ALL: Significant Commercial Opportunity

CML and ALL: Large Markets

CML **89,226** US patients
8,930 new patients/year

ALL **111,425** US ALL patients
6,540 new patients/year

Robust Commercial Opportunity

$3.7B **CML and ALL** market value

12% **CML** market growth per year

53% **SPRYCEL** branded market share in CML market

$206,568 **SPRYCEL** annual treatment cost (WAC, 2023)

$2.2B **SPRYCEL** 2023 projected revenue

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Value Proposition Supported by Both Prescribers and Payors

DASYNOC Value Proposition

✓	Precision Pharmacokinetics	✓
✓	No Drug-Drug Interaction	✓
✓	Comparable bioavailability at 30% Lower Dose	✓
✓	Potential Safety Improvement	✓
✓	Premium Product without Premium Pricing	✓

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EVERSANA™ Platform for XSpray success

100% **XSpray revenue** remains with the company

Fee for **service model**

Infrastructure for commercialization **not required**

Licensing **partnerships avoided** to maximize and maintain Xspray's value

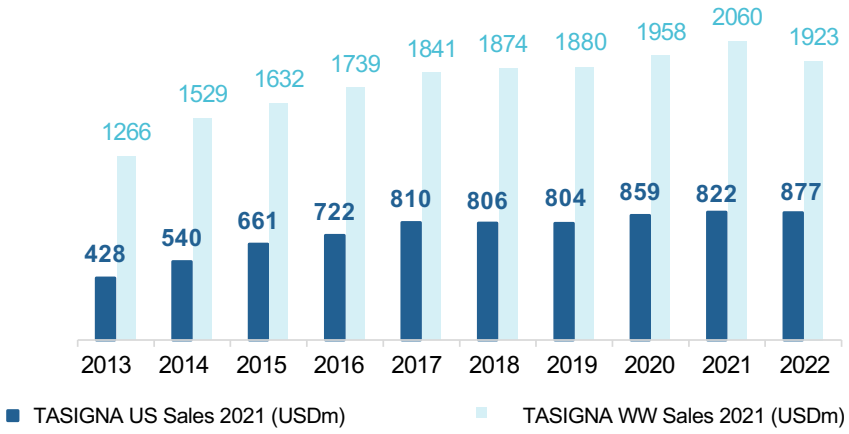
Harness experienced **commercial teams**, existing **customer base** and payors, utilize **distribution channel**

Scaleable flexibility to add/manage resources

Platform for **future commercialization**, easily **add products**, leverage existing efforts, **expand** into future campaigns

TASIGNA: Important CML Medication with Important Limitations

TASIGNA for CML: 30% market share in the US



30%
TASIGNA's market share in the US CML market

USD 877m
TASIGNA's 2022 US sales for CML

USD 1,923m
TASIGNA's 2022 worldwide sales for CML

TASIGNA limitations

31% patients requiring permanent dose reduction due to initial side effects/tolerability issues[1]

32% self-reported non-adherence to TASIGNA treatment[2]

27% non-compliance with administration under fasting conditions[2]

(1) Tribelli et al 2018, (2) Boons 2019

Boxed Warning
WARNING: QT PROLONGATION AND SUDDEN DEATHS
Patients must avoid food for 2 hours before and 1 hour after each dose

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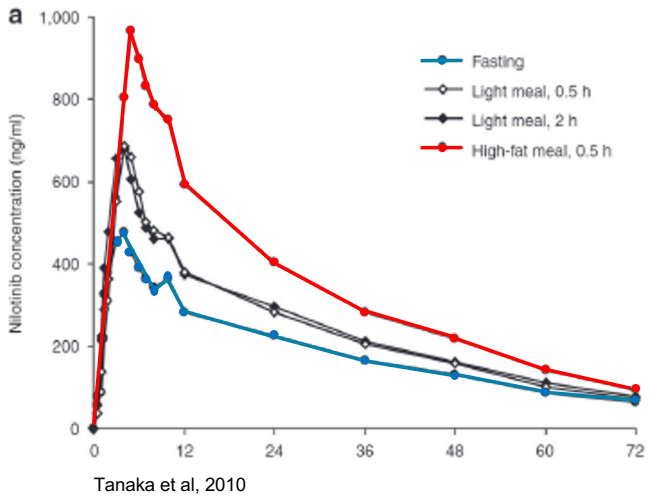
XS003 (amorphous nilotinib): Premium Version of TASIGNA

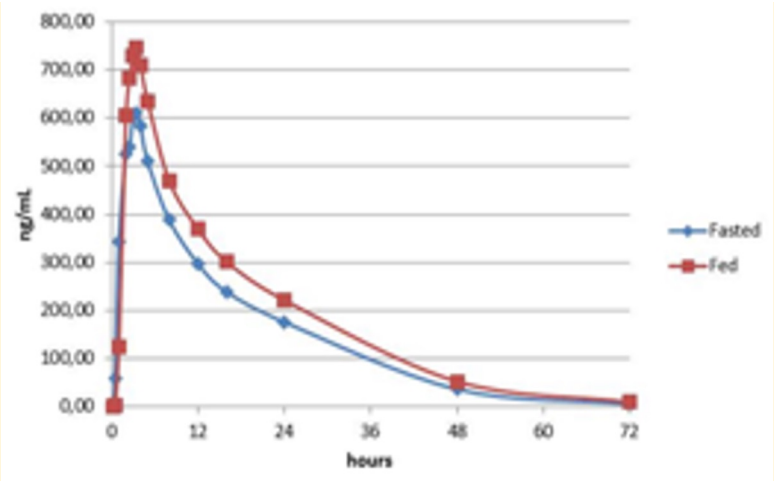
XS003 Provides consistent delivery nilotinib to improve the efficacy and safety of TASIGNA

Tasigna



Tanaka et al, 2010

XS003



XS003 optimizes TASIGNA

- Greater bioavailability
- Lower dose strengths
- Decreased exposure variability
- Eliminates clinically relevant food effect
- No expected drug-drug interactions using PPI's
- Composition of matter patent expiry January 2024

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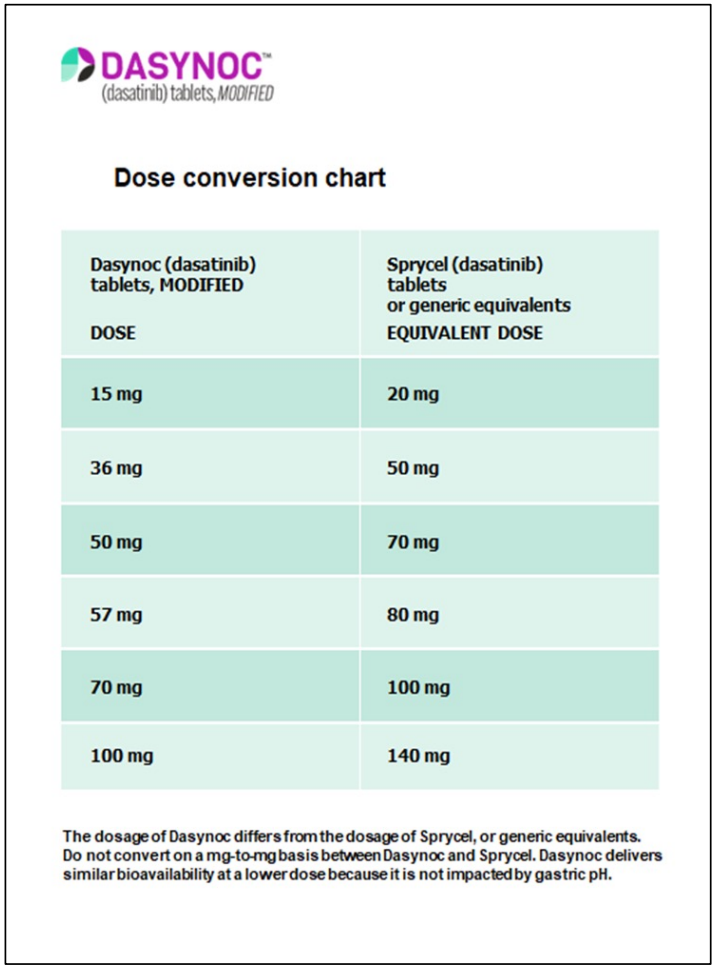
DASYNOC (dasatinib) - Current Situation

- Ongoing FDA pre-approval inspection at third part manufacturing site.
- Complete Response Letter (CRL) received on July 10, 2023.
- FDA meeting held on September 6, 2023.

Actions remaining to reach DASYNOC FDA approval:

- Response to dasatinib CRL Dec 2023/Jan 2024
- Maximum 6 months review by FDA.
- Pre-Approval inspection to be closed.



DASYNOC™
(dasatinib) tablets, MODIFIED

Dose conversion chart

Dasynoc (dasatinib) tablets, MODIFIED DOSE	Sprycel (dasatinib) tablets or generic equivalents EQUIVALENT DOSE
15 mg	20 mg
36 mg	50 mg
50 mg	70 mg
57 mg	80 mg
70 mg	100 mg
100 mg	140 mg

The dosage of Dasynoc differs from the dosage of Sprycel, or generic equivalents. Do not convert on a mg-to-mg basis between Dasynoc and Sprycel. Dasynoc delivers similar bioavailability at a lower dose because it is not impacted by gastric pH.

Executive Summary

DASYNOC

The Dasatinib You Know, Now Consistently Delivered

All patients require and deserve consistent delivery of dasatinib to optimize its full clinical potential

- Lead asset on track for FDA approval and commercial launch in September 2024
- Strong patent position
- Premium product profile to reference drug SPRYCEL® (crystalline dasatinib)
- Parity pricing to SPRYCEL
- Excellent prescriber and payor acceptance
- Strong commercial partner
- Commercial platform for additional follow-on products

SPRYCEL US market value: $2.2bn/y
Xspray post approval burn rate: $0.06bn/y
Requires merely 2.7% market share for breakeven

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