Hyloris PHARMACEUTICALS

Reformulating the Future

2021 Full Year Results

16th of March 2022

Forward-Looking Statements

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Agenda for Today's Call

- Hyloris: geared for growth
- Business update
- Financial results Full Year 2021
- Outlook for 2022
- Q&A

Rethinking, Reinventing, Optimising Existing Medications

To improve overall therapy outcomes

REFORMULATING

Changing dose or route of administration

REPURPOSING/
REPOSITIONING

Finding new indications

For the benefit of patients, physicians, payors

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Faster Innovation at Considerably Lower Costs and Risks

Discovery, pre-clinical development | **Clinical Development** | **Regulatory submission & decision**

15 YEARS ON AVERAGE
$1.3 BILLION COSTS ON AVERAGE

"Traditional Pharma-Biotech Model"

Feasibility, formulation, production | **Clinical Development** | **Regulatory submission & decision**

≤ 7 YEARS
≤ €7 MILLION COSTS ON AVERAGE*

"505(b)(2) value-added medicines"

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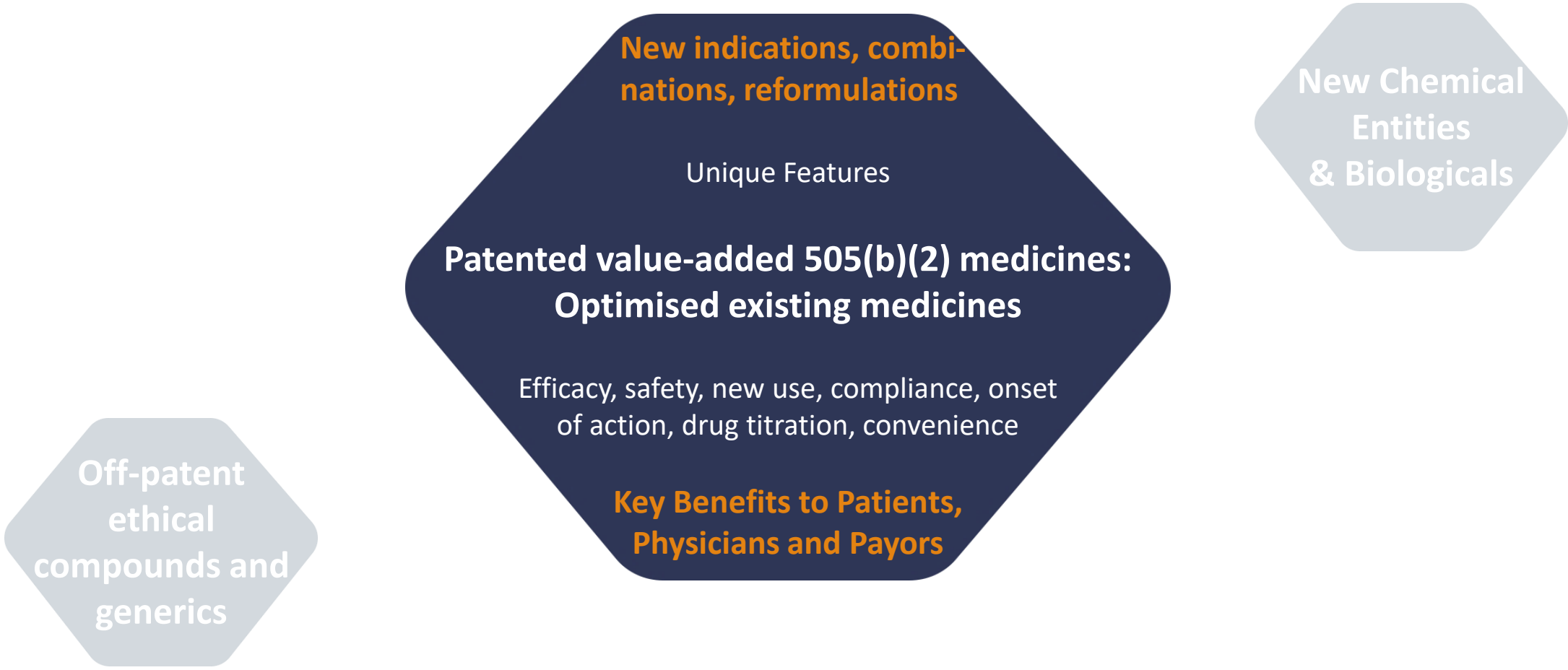
Traditional R&D model: Wouters *et al*, Journal of the American Medical Association, 2020
* Hyloris budget

Patented Value-Added Medicines: Pharma's Sweet Spot



Hyloris: Key Investment Highlights

Growth Pillars

15[1] patented product candidates in the pipeline

Spread across stages and indications

Expand with 4 products on average per year

MULTIPLE SHOTS ON GOAL

2 products on the market with partners

Build own, lean, commercial organisation in the U.S.

Addressing large areas of unmet medical needs

COMMERCIAL PORTFOLIO

Patients, partners, physicians and KOLs

Real-world data and payors' input

Outsourcing of non-core activities

VALUED PARTNERS

1 excluding high barrier generic products HY-038, HY-016 and Fusidic Acid Cream

Broad, Innovative Portfolio*: Expand to ~30 Assets by 2024

Product	Route of Administration	Indication	Formulation and Manufacturing	Clinical Development	Regulatory Filing	Target Market
CARDIOVASCULAR (CV) PORTFOLIO			**Up to 7 years**			
Sotalol IV	IV	Atrial fibrillation	***Launched in U.S./partnered with AltaThera***			
Aspirin IV U.S.	IV	Acute coronary syndrome				
Milrinone	Extended Release Capsule	Advanced heart failure (LVAD)				
Dofetilide IV	IV	Atrial fibrillation				
Metolazone IV	IV	Congestive heart failure				
HY-074	IV	Acute coronary syndrome				
HY-075	Oral Liquid	Coronary heart disease				
OTHER VALUE-ADDED PORTFOLIO			**Up to 7 years**			
Maxigesic® IV	IV	Post-operative pain	***Licensed in >100 countries/partnered with AFT Pharmaceuticals***			
TXA RTU	IV	Excessive bleeding				
HY-004	Oral Liquid	Specific dental indication				
Miconazole-DB	Topical	Severe and rVVC				
Plecoid™ Agent	IV	AML/SCLC				
Alenura™	PFS	IC / PBS				
Atomoxetine	Oral Liquid	ADHD				
HY-029	Oral Liquid	Viral infection				

**** Our high barrier generic products, HY-038, HY-016 and Fusidic Acid Cream have not been included in the above overview***

Intended to be commercialised by Hyloris in the U.S.
Intended to be commercialised with partner

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Aspirin IV U.S. is formerly known as HY-073
IV: intravenous ; RTU: ready to use; IM: intra-muscular

LVAD: battery-operated, mechanical surgically implanted pump, which helps the left ventricle of the heart pump blood TXA: tranexamic acid; ADHD: attention deficit hyperactivity disorder; Miconazole-DB: miconazole-domiphen bromide ; rVVC: recurring vulvovaginal candidiasis; AML: Acute Myeloid Leukemia; SCLC: Small cell Lung Cancer

Two Commercialised Products

Maxigesic® IV:
Significant Growth of Commercial Footprint

Sotalol IV:
Expanded Sales Force to Foster Growth

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Maxigesic® IV: Significant Growth of Commercial Footprint

AFT pharmaceuticals + strong local distribution partners – Global coverage and gradual roll-out

Countries	**2022**
Licensed	100+
Registered	33
Launched	7

- Launched in South Korea, Panama, Germany and Austria
- License agreement with Hikma in the U.S.
- Europe: additional licenses and approvals
- Patents granted across multiple jurisdictions
- FDA – PDUFA date - 30 June 2022

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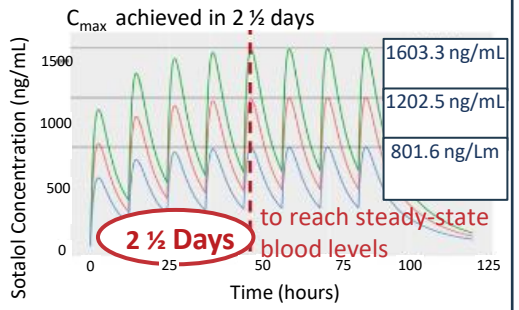
Sotalol IV: Expanded Sales Force to Foster Growth

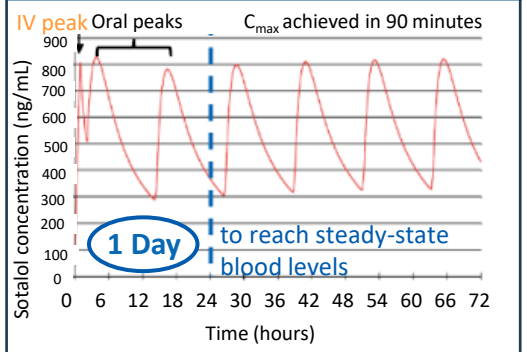
- Expansion of AltaThera's sales force to accelerate roll-out in the U.S.

Fast onset, particularly crucial in acute AF settings

Oral sotalol initiation

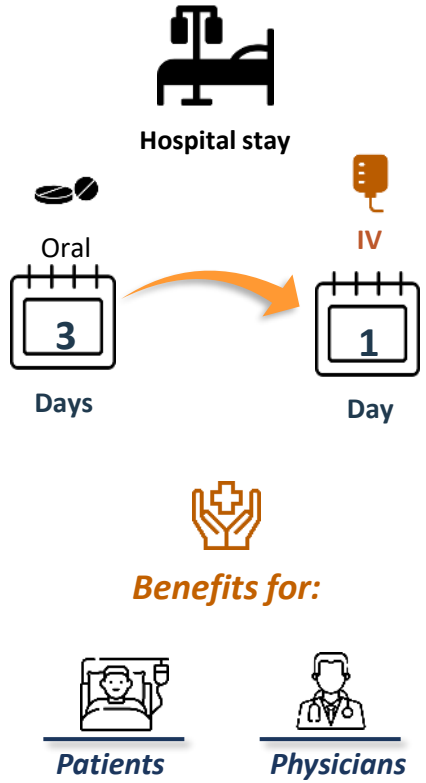


Sotalol IV loading dose



Steady state blood level after in 1 day with Sotalol IV (vs. 2.5 days with oral)

Hospital stay monitoring significantly reduced



Significant cost reduction potential

AF incremental cost saving

Opportunity for premium pricing compared to the generic oral formulation

AF: atrial fibrillation

4 innovative product candidates added in the portfolio

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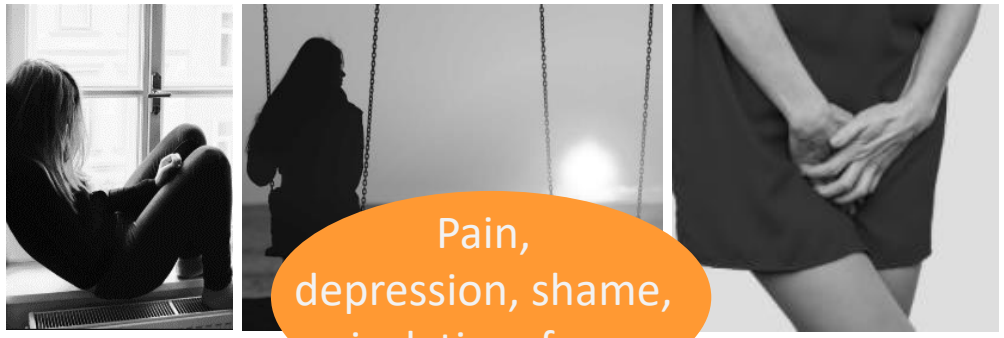
1. Unmet Needs in Severe and recurrent vulvovaginal candidiasis (rVVC)
2. Oral Milrinone capsule in heart failure (HF) with left ventricular assist device (LVAD)
3. Alenura™ for treatment of acute pain in interstitial cystisis (IC) and bladder pain syndrome (BPS)
4. Plecoid™ Agents for patients with acute myeloid leukemia (AML) and small cell lung cancer (SCLC)

1. Unmet Needs in Severe and rVVC



Current medicines have limitations

Local **Systemic**

Treatment of acute VVC episodes - side effects

Vulvovaginal candidiasis (VVC)

- Infection caused by *Candida* sp. yeast
- Causes irritation, vaginal discharge and intense itchiness
- **Affects 50% of all women** during their life
- ~175 million drug products sold/year

Severe and recurring VVC

- **10% of all women globally**
- No effective treatments: drug-resistant biofilm
- $14.4 Bn annual estimated economic burden

No innovation over the past few decades

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G. Pappas *et al*., Clinical Infectious Diseases (2016); J.D. Sobel *et al*., Expert Opinion on Pharmacotherapy (2018)
Janssen-Cilag Ltd is the marketing authorisation holder of Gyno-Daktarin

Miconazole-DB has Potential to Cure Severe and rVVC

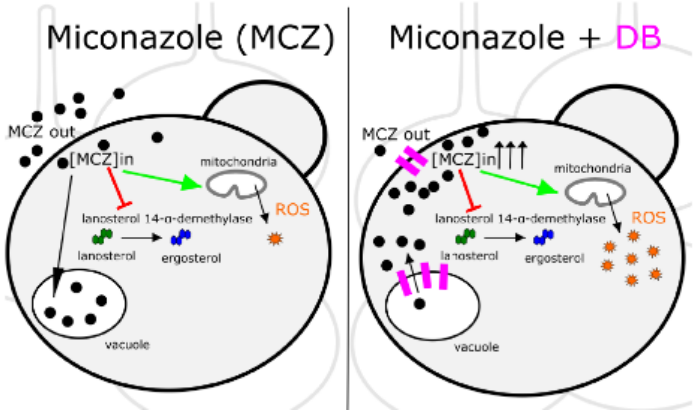
WELL-KNOWN ANTIMYCOTIC
MICONAZOLE (MCZ)
Prevents growth of fungus

REPURPOSED MOLECULE
DOMIPHEN BROMIDE (DB)
Potentiator for fungicidal activity

Domiphen-bromide: anti-septic; identified as a miconazole potentiator through drug screening of large *drug repurposing library*

DUAL FUNGICIDAL ACTIVITY

LOCAL TOPICAL FORMULATION



Unique mode-of-action

Domiphen Bromide (DB):

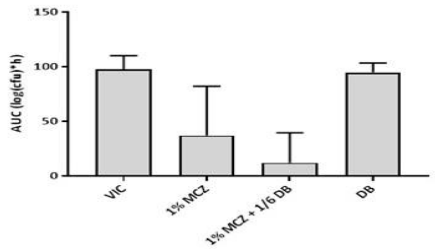
- Enables increased MCZ uptake in *Candida* cells at low doses
- Alters cytoplasmatic distribution of high azole doses
- Negatively affects vacuole integrity, thereby releasing vacuole-sequestered MCZ

Increased intracellular azole availability results in

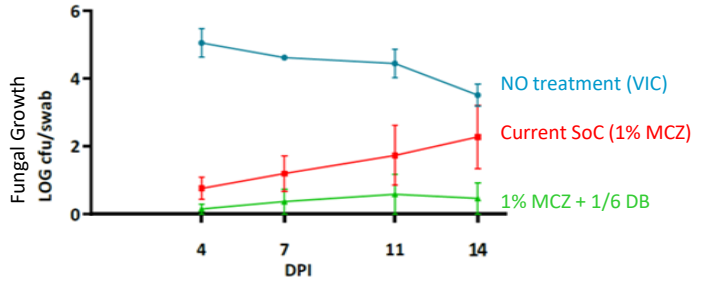
- Increased ROS* generation = apoptosis
- Fungicidal antibiofilm activity

** ROS = reactive oxygen species*

PURNA PHARMA



Infection expressed in area under the curve (AUC) after 4 days of treatment and 10 days of follow-up in function of different formulations



Intravaginal fungal burden in log colony forming units (cfu) per swab during different therapies expressed in days post-infection (DPI)

Domiphen Bromide significantly enhances Miconazole efficacy *in vivo*

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Benhamou R. I., *et al*, ACS Chemical Biology, 2017

J. Tits., J *et al.*, Antimicrob Agents Chemother (2020) ; K. De Cremer *et al*., Antimicrobial agents and chemotherapy (2015)

Deal Structure and Next Steps

Purna Female Healthcare (PFH)

- Belgian based spin-off (Purna Pharmaceuticals and Creafund).
- Completed early-stage R&D activities with University of Antwerp and KU Leuven, including all pre-clinical work and responsible for further product development, clinical trials, manufacturing, regulatory affairs, IP.
- IP and know how in-licensed from University of Antwerp and KU Leuven.

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- Committed to milestone related investments of up €4.27M, of which €1.27M at signing, and to support PFH.
- Owns 20% of PFH, eligible to receive up to a maximum of 45% of the net profits generated by PFH.
- Responsible for out-licensing and commercialization.

Started Phase 2 clinical study in 2021

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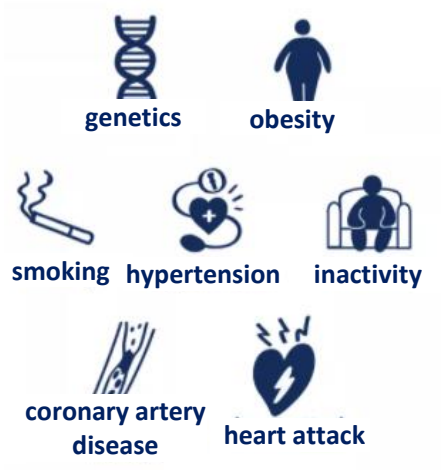
2. Heart Failure: #1 Cause of Hospitalisation in people >65 years

Heart failure (HF) occurs when the heart is unable to pump enough blood through the body

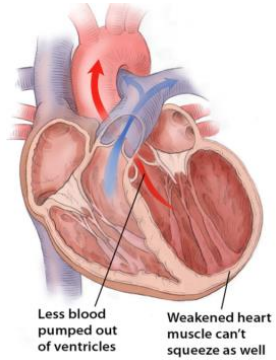
Causes and Risk Factors



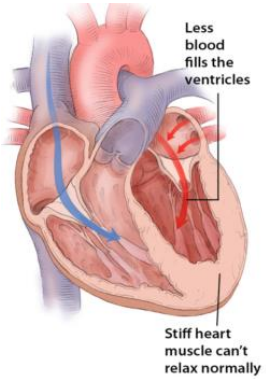
Symptoms

2 Types

HFrEF (thin, weak heart muscle)
Heart failure with reduced ejection fraction



HFpEF (thick, stiff heart muscle)
Heart failure with preserved ejection fraction



By 2030, the annual HF-related cost in the U.S. is expected to be $70 Bn ($210/inhabitant)

50% incurred in the hospital

HFrEF: heart failure with reduced ejection fraction; HFpEF: heart failure with preserved ejection fraction
Ejection fraction is the amount of blood leaving the heart at every contraction, normal EF is >50 %, reduced EF < 40 %

HF Classification and Disease Management

As the condition gets worse, the heart muscle pumps less blood to the organs, and the patient moves toward the next stage of heart failure

STAGE	MANAGEMENT STRATEGY
STAGE A: **At risk for developing HF**	• Urge lifestyle modification (e.g. diet, weight loss, exercise) • Treat comorbidities (e.g. hypertension, diabetes, hyperlipidaemia, atrial fibrillation)
STAGE B: **Asymptomatic** *with structural heart disease*	• Continue to treat comorbidities and recommend lifestyle changes • Monitor for development of HF symptoms **Additional treatment for reduced EF patients only** • Initiate beta blockers and ACE inhibitors or ARBs • Use implantable cardioverter-defibrillators (ICD) in post-MI patients
STAGE C: **Symptomatic** *Prior or current HF symptoms*	• Continue to treat comorbidities and recommend lifestyle changes • Educate patients on self-care (e.g. salt restriction and HF symptoms) **Additional treatment for reduced EF patients only** • Initiate beta blockers and ACE inhibitors or ARBs with diuretics • ICDs or cardiac resynchronisation therapy
STAGE D: **Refractory or advanced HF**	• Refer to cardiology for advanced therapies such as left ventricular assist device (LVAD) or heart transplant • In-patient, short-term use of IV inotropes (such as IV Milrinone) for severe decompensated HF patients • Discuss end-of-life treatment goals as appropriate

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American College of Cardiology Foundation and American Heart Association; Triangle Insights 2016
EF: ejection fraction; ACE: angiotensin converting enzyme; ARB: angiotensin receptor blocker
Structural heart disease: left ventricular (LV) hypertrophy, LV dysfunction, prior myocardial infarction (MI) or vascular disease

IV Milrinone: Positive Inotrope = Increases Contractility

CARDIOPULMONARY EFFECTS:

- Increased contractibility and heart rate.
- Increased stroke volume and ejection fraction.
- Increased cardiac output.
- Decreased peripheral and pulmonary vascular resistance.

Currently approved for use as an intermittent or continuous infusion for treatment of up to 48 hours for acute decompensated heart failure.

Longer term off-label use exceeding 48 hours of treatment duration has been reported, requiring nursing support.

Market: >12 million vials and infusion bags sold in 2020, of which >2 million in the U.S. alone.

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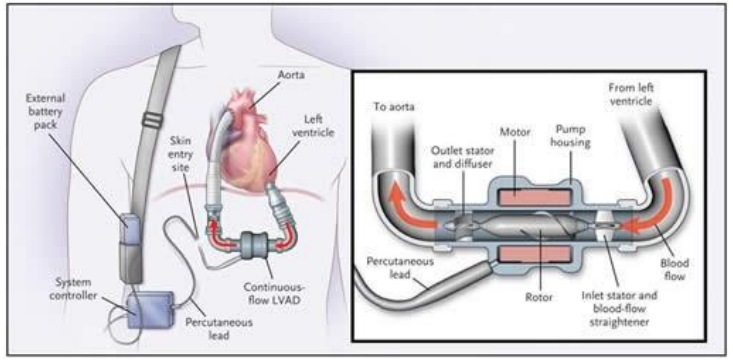
Oral Milrinone: Our Potential Solution in LVAD RHF Patients

Epidemiology



~20,000 patients with an LVAD; 6% average annual growth rate expected over next years[1]

30% will develop

right HF (RHF)

- Associated with very poor outcomes, including increased morbidity and mortality
- May require IV inotropic treatment

IV Milrinone: shortcomings

- Cumbersome, limiting patients' QoL
- High readmission rates post discharge
- High cost of care
- Not approved for long term use

Oral Milrinone
Orphan Drug Status in U.S. in LVAD RHF

- Novel, orally administered extended-release capsule
- Positive results from earlier clinical studies: linear dose-response PK; well-tolerated and encouraging signs of effect in prolonged compassionate use phase*

This could potentially:

- Improve QoL
- Significantly reduce cost of care: lower readmission rates and faster discharge; administer at home by the patient for longer term use

CRD-102 has the potential to address the shortcomings of IV Milrinone in end-stage HF

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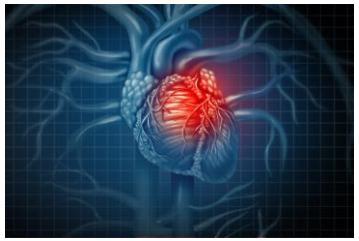
[1] Grand View Research Inc 2021; [2] Triangle Insights 2016
* Nanayakkara et al. Am J Cardiol. 2018; Nanayakkara et al. J. Am. Heart Assoc. 2020; LVAD study results: publication pending

Oral Milrinone: Partnership with The Baker Institute

To develop and commercialise a novel, patient-friendly oral formulation of Milrinone to meaningfully improve the lives of patients with advanced HF and significantly reduce cost of care



Scope

- HYL to acquire worldwide rights to CRD-102, a novel oral formulation of Milrinone in patients with advanced HF
- Potential to replace Milrinone IV and overcome current shortcomings to significantly improve the lives of patients with advanced HF and reduce cost of care

Financial terms

HYL to pay the Baker Institute:

- $50K upfront signing fee
- In markets where HYL will self-commercialise: i) tiered single digit net profit share; ii) sales-based milestone payments
- In markets where HYL will seek commercial partnerships: tiered net profit share of net sub-license income

Responsibilities

- HYL responsible for product development, manufacturing, regulatory affairs and commercialisation
- The Baker Institute to provide R&D support

Start of clinical study expected in 2023

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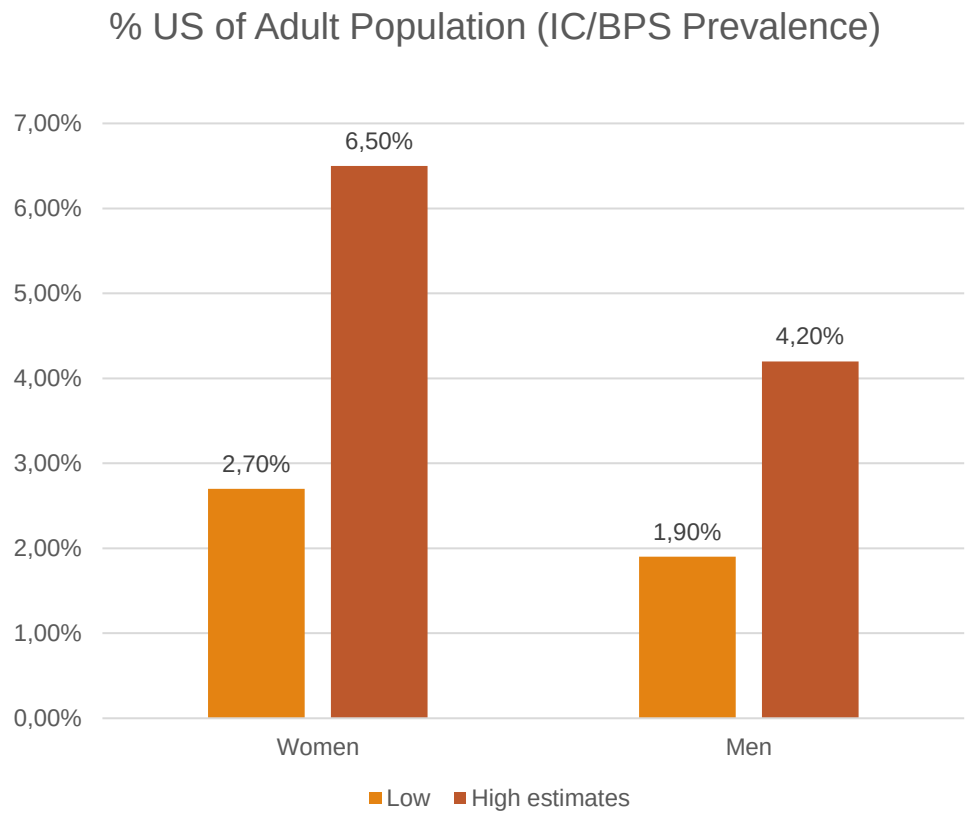
3. Alenura™ for treatment of acute pain in IC/BPS – Large market

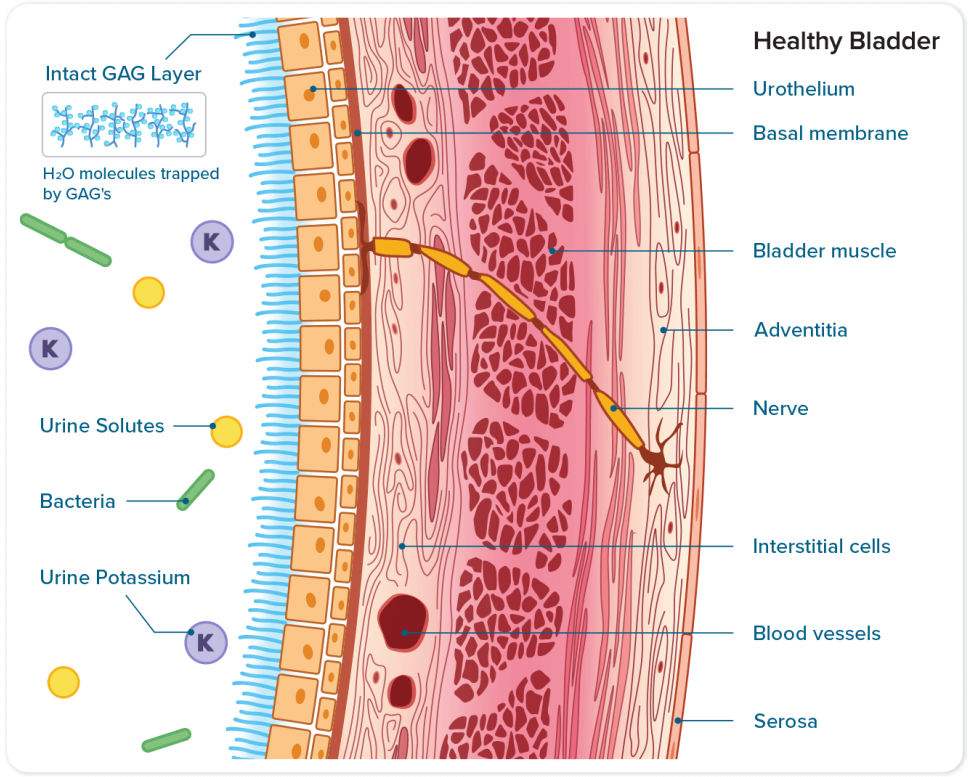
- Interstitial Cystitis / Bladder Pain Syndrome (IC/BPS) is a condition that results in recurring discomfort or pain in the bladder and surrounding pelvic region.
- IC/BPS stems from an anatomical defect in the protective bladder lining (the GAG layer) which exposes nerve endings to toxic components in urine.
- Affects at least 6 million people in the U.S.
- IC/BPS is more predominant in women[1], although men can experience symptoms as well.
- Existing market underdiagnosed, there are no products approved to treat acute pain in IC/BPS
- 3 million instillation procedures/year in the U.S.



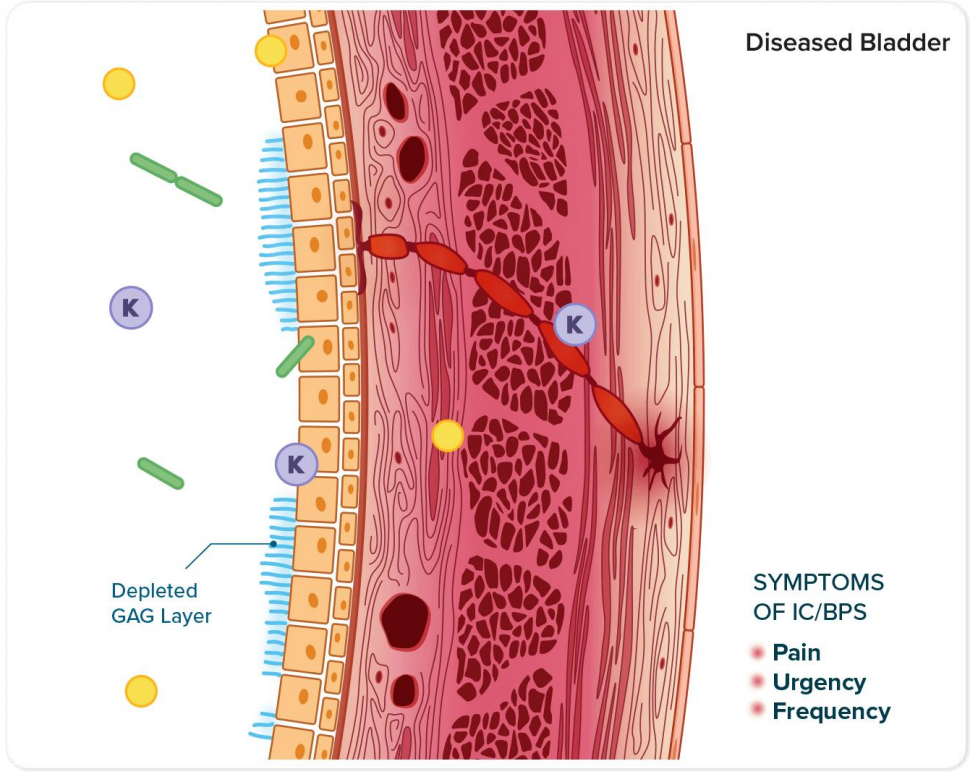
[1] Data on female population is from RAND Study: J Urol. 2011 August, 186(2): 540–544. doi:10.1016/j.juro.2011.03.132

Cause of damage, inflammation and pain

Healthy bladder



Diseased bladder



Loss of the protective GAG layer exposes the urothelium to toxic components in urine, including potassium that can infiltrate underlying tissue causing damage, inflammation and pain

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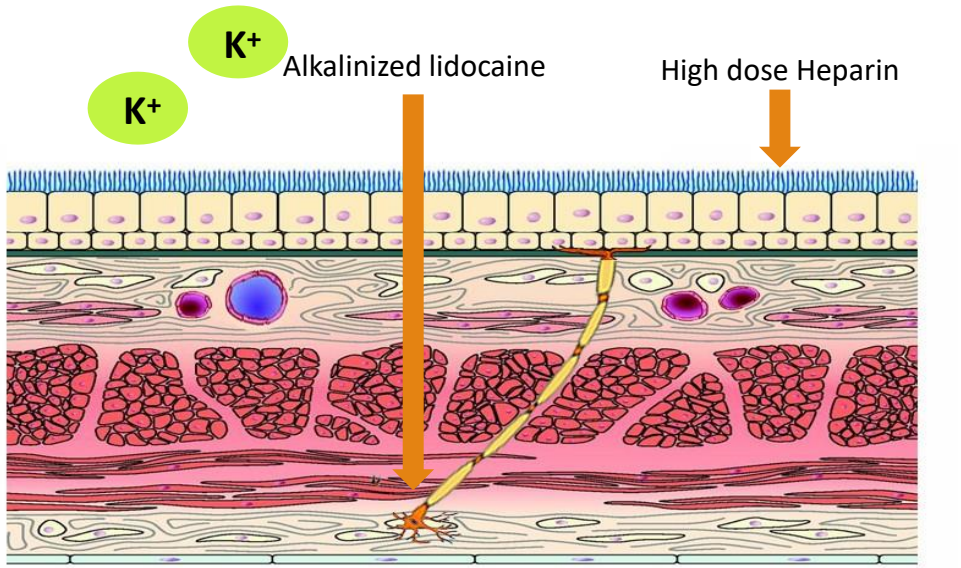
Novel, dual mode of actions candidate to IC/PBS



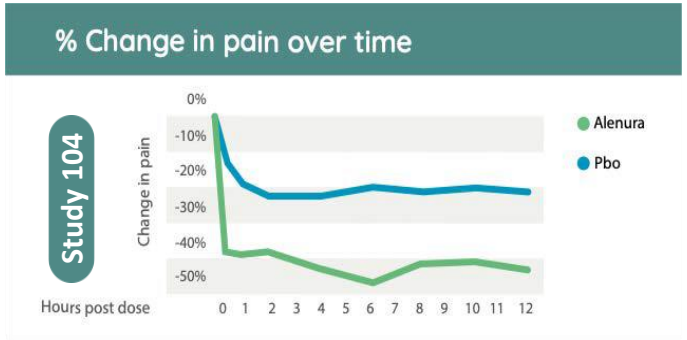
Alkalinised lidocaine: penetrates the bladder wall and provides immediate pain relief

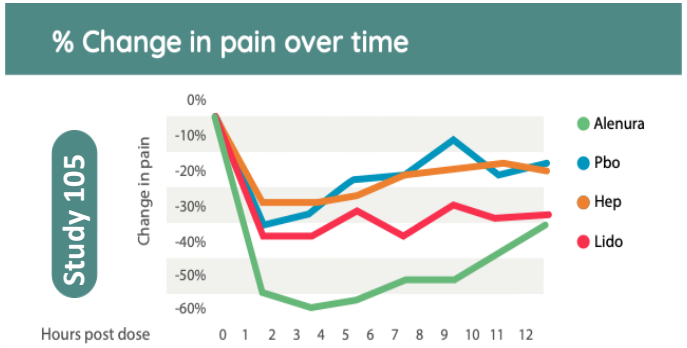
+

Heparin: augments bladder mucous, prevents further irritation, and has anti-inflammatory and anti-bacterial properties

Pain relief and reinforcement of mucous layer

- Alenura 15mL prefilled syringe: unique combination of alkalinised lidocaine + heparin to use as instillation product
- Proven efficacy in 2 controlled Phase 2 trials





In a phase 2 trial, Alenura™ consistently demonstrated significant superiority versus placebo. Pain relief with Alenura™ exceeds that of its individual components alone, and has excellent safety and tolerability

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Deal Structure and Next Steps

- Vaneltix will be responsible for the further development, manufacturing, regulatory affairs and commercialisation of Alenura™ in collaboration with Hyloris.
- Hyloris will provide staged investments up to USD 6.7 Mio for Phase 2, manufacturing and regulatory related activities and a loan of USD 0.5 Mio.
- Objective to out-license the product after successful Phase 2.
- Hyloris will be eligible to receive a tiered percentage of the product margin generated by Vaneltix.

- Start of a larger Phase 2 clinical trial mid 2022 for which the results could be available by late 2023.
- Due to expected efficacy, limited size Phase 3 studies required.

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4. Plecoid™ Agents when chemotherapy is not enough

- Acute Myeloid Leukemia (AML) is a relatively rare disease with a worldwide incidence of about 160.000 cases[1]. For patients above 20 years old, the 5-year survival rate is around 26%[2]. In the US, there is an estimate of 20.050 new cases of AML in 2019 and 11.400 deaths.
- 13%-15%[3] of 2 million cases of lung cancer per year are diagnosed with SCLC globally with a 5-year survival rate around 5%.
- Any significant improvement in overall response rate and survival in the SCLC and AML population would constitute a real progress in clinical practice.

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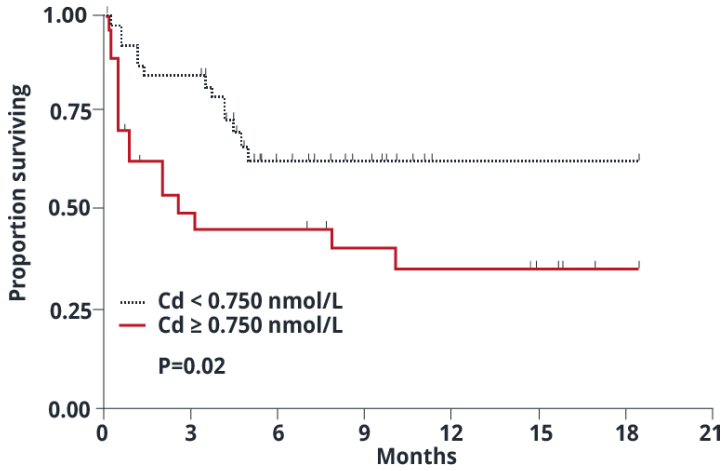
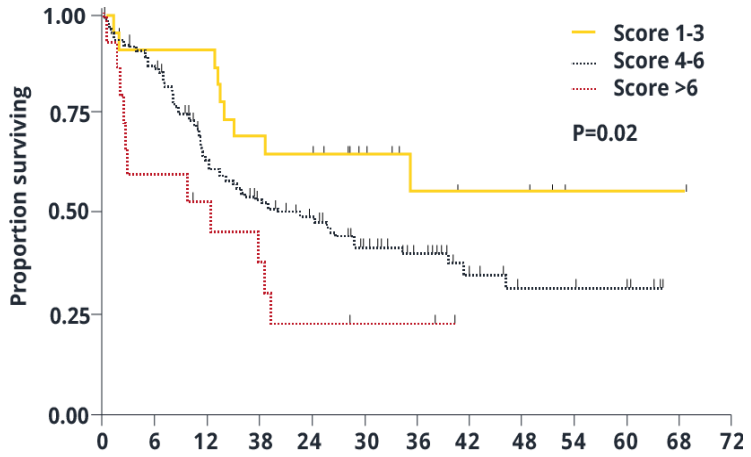
1 Datamonitor Healthcare April 2021; Leukemia & Lymphoma Society, 2019; WHO classification of AML, 20161
2 https://www.cancer.net/cancer-types/leukemia-acute-myeloid-aml/statistics
3 Medscape - Abid Irshad, MD Associate Professor, Department of Radiology, Medical University of South Carolina College of Medicine2

Toxic Metals in Tumour Micro-Environment Impact Survival

- Significant elevations of toxic metals have been detected in the bone marrow and blood of patients with Acute Myeloid Leukemia (AML) .
- High levels of toxic metals are associated with inferior survival.



Overall survival in AML patients with **high** and **low** serum cadmium levels



Overall survival in AML patients by groupings of metal scores

Many metals are implicated in disease progression: survival significantly worse in patients with higher metal scores

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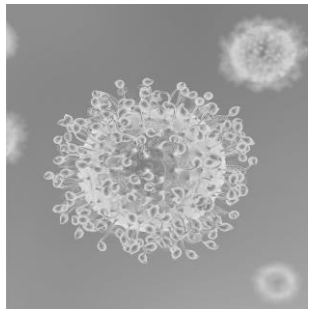
M. Ohanian et al, American Journal of Hematology, January 2020

Plecoid™ Agents: Partnership with Pleco

First-in-class product to boost chemotherapy:

- Based on breakthrough research
- Designed to detoxify the cancer-promoting micro-environment
- Strong IP protection
- Achieved clinical proof-of-concept in AML patients



Scope	Financial terms	Responsibilities
• HYL gains exclusive rights to a Plecoid™ Agent in AML, with further development and commercialisation commitment subject to regulatory feedback • HYL can opt-out after regulatory feedback • Potential to expand to include Small Cell Lung Cancer (SCLC)	• HYL to provide €1M upfront loan/equity investment in return for exclusive rights to a Plecoid™ Agent in AML • Subject to regulatory feedback, HYL to provide maximum €6.7M R&D funding up to regulatory submission in AML in the U.S. • HYL eligible to receive up to 65% of net sales	• HYL responsible for CMC activities; co-responsible for licensing/commercial activities; co-responsible (and co-own) for IP • Pleco responsible for product development and regulatory affairs; co-responsible for licensing/commercial activities; co-responsible (and co-own) for IP • Joint steering and decision-making committee

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Financial Highlights: Year end 2021

(in € thousand)	FY 2021	FY 2020	% change
Revenues	**3,096**	**175**	**1669%**
Operating expenses	**(13,337)**	**(3,626)**	**149%**
R&D expenses	(5,056)	(3,413)	48%
G&A expenses	(2,900)	(3,662)	(20.8%)
Other (one-off expenses)	(5,381)	21	NA
Net cash (burn)/inflow[i]	**(14,387)**	**64,194**	**NA**
Cash and cash equivalents	**50,012**	**64,399**	**(22.34%)**

- Revenues: growth mainly driven by Maxigesic IV and Sotalol IV
- Operating expenses:
  - R&D expenses according to plan
  - G&A 2020 impacted by IPO costs
  - One-off expense related to unwinding of agreements with the Alter Pharma Group

- Cash burn:
  - HY21: impacted by one-off cash outflow related to unwinding of agreements with Alter Pharma Group
  - HY20: positively impacted by financing activities (convertible bonds and IPO)

[i] For the period 1 January to 31 December

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Core Assets: Anticipated Value Inflection Milestones in 2022

Clinical

- Starting and completing pivotal PK clinical trial for Aspirin IV
- Starting pivotal PK clinical trial for Dofetilide IV and HY-029
- Starting Phase 2 clinical trial for Alenura™
- Completing Phase 2 clinical trial for Miconazole-DB in H2 2022
- Starting Phase 3 clinical trial on HY-004

Regulatory

- Maxigesic® IV: PDUFA date 30 June 2022
- Atomoxetine: implementing changes to taste masking technology – FDA scientific feedback

Commercial

- Commercial partnership(s)
- Continue roll-out of Maxigesic® IV and Sotalol IV with our partners

Ambition to expand the product portfolio to ~30 assets by 2024, of which min 4 new candidates in 2022

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Unique Value Proposition

- Two commercial products with long runway for growth.
- Broad product candidate portfolio (6 cardiovascular and 7 other value added) supporting long-term growth.
- Strategic objective to expand to ~30 product (candidates) by 2024, primarily repurposed.
- Lean and smart operating model based on stringent 7-7 development criteria expected to provide strong return on investment.
- EUR 50 million cash to fund product portfolio development.

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Q&A

Contact us:
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