## **adjucenne** Corporate Presentation Q3 2024

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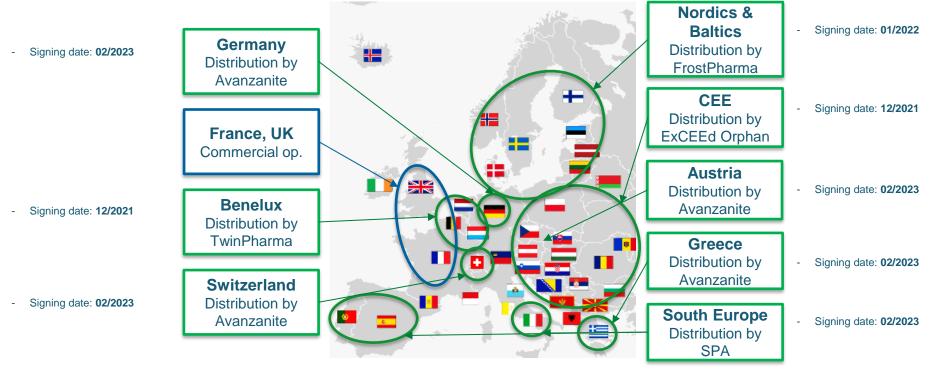


## Sibnayal<sup>®</sup> / ADV7103 commercially available

- Commercial launch in EU and UK for the treatment of dRTA (distal Renal Tubular Acidosis) in pediatric (from one year of age) and adult patients
- **H1 2024 gross sales**: 1.28M€ up 28%
- Around 10 patients gain per month on average
- Distribution partnerships covering Europe and MENA
- On-going pricing discussions in most of European countries, except Denmark, Scotland and Slovakia



#### ...and supported by an extended distribution platform



Other partnerships in MENA region: partnership with Taïba Healthcare (Signing date: 06/2022) in Saudi Arabia, Oman, United Arab Emirates, Qatar, Kuwait and Bahrain Sibnayal mainly sold through hospital channels

# ADV7103: a breakthrough alkalinizing asset for rare renal diseases

- **Patented** prolonged release **combination** of potassium citrate (CK) and potassium hydrogen carbonate (bicarbonate BK) enabling **twice-daily dosing**
- Only convenient chronic oral treatment (>6-year European follow-up data):
  - Sustained efficacy
  - Strong treatment compliance
  - Very good safety profile



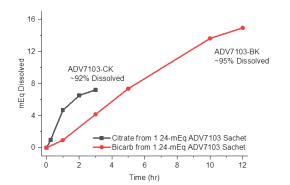
	✓ Centralized market approval in EU and the UK (Commercial name: Sibnayal <sup>®</sup> )
dRTA <sup>(1)</sup>	✓ Orphan Drug Designation in the US
	✓ NDA approval process in discussion with the FDA
Cystinuria	<ul> <li>Phase III clinical plan to be agreed with EU and US agencies</li> <li>Orphan Drug Designation in the US</li> </ul>

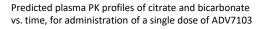
<sup>(1)</sup> distal Renal Tubular Acidosis is a rare but serious chronic disease characterized by the increase of acid ions in the blood

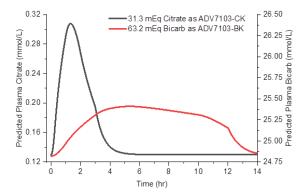
### **ADV 7103: Designed to Change Patient's Lives**

- **ADV7103: Fixed combination** of potassium citrate(CK) and potassium bicarbonate(BK)
- Sequential and prolonged release of CK and BK enabling 24 hour pH control from twicedaily dosing

Dissolution curves for ADV7103 CK (Citrate) and BK (bicarbonate)



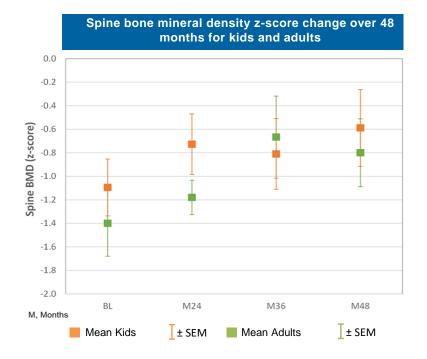




- Mean bicarb plasma levels maintained in normal range over 6 years- B22CS
- 27/30 subjects remained on treatment after 6 years in long term study – B22CS
- Mean adherence rates >70% (excellent) for majority of long-term study subjects
- >70% patients prefer to SOC – GOSH cohort



### **ADV7103: Impactful on Long-Term Bone Growth**



#### Analysis of covariance of z-score

#### Statistically significant incremental improvement

- Significant increase of z-score in spine BMD compared to baseline (ANCOVA) for both kids and adults (24 patients)
- At month 24: LS mean difference estimate [95% CI] of 0.22 [-0.01, 0.44] units (p=0.0573)
- At month 36: LS mean difference estimate [95% CI] of 0.31 [0.08, 0.54] units (p=0.0103\*)
- At month 48: LS mean difference estimate [95% CI] of 0.36 [0.13, 0.60] units (p=0.0038\*)

\*Statistically significant

source: Bertholet-Thomas et al. Efficacy and safety of an innovative prolonged-release combination drug in patients with distal renal tubular acidosis: an open-label comparative trial versus standard of care treatments. Paediatric Nephrol. 2021 Jan;36(1):83-91.

source: Safety, efficacy, and acceptability of ADV7103 during 24 months of treatment: an open-label study in paediatric and adult patients with distal renal tubular acidosis. Paediatric Nephrol. 2021 Jul;36(1):1765-1774.



## **ADV7103: Strong Business Protection**

- ADV7103 is protected by 3 family patents covering formulation, including the patent that covers the combination of potassium citrate and potassium bicarbonate in a delayedrelease formulation
- Initial patents expiration date: November 2031 in USA and Europe



- Since the approval of ADV7103 in EU and the UK, relevant patent terms have been extended through Supplementary Protection Certificate (SPC) by 5 years (until 2036) in France, GB, Italy and Spain.
- 6-month Pediatric exclusivity extension



ADV7103 eligible for Patent Term Extension (PTE)



#### Advicenne Regulatory Strategy has led to early NDA Filing

Advicenne has convinced FDA of a possible filing by leveraging EU clinical data and KOL support

#### Long term safety and efficacy data from EU

- B21: demonstrated long-term control of metabolic acidosis with very good safety and tolerability profiles
- B22: long term follow up trial with 27 patients followed up to 72 months with supportive data on growth and renal function preservation.
- > No safety or pharmaco-vigilance event since European commercial launch

#### FDA convinced by long term safety and efficacy data from EU

- > No further US clinical study required for NDA filing
- > A pathway now exists to submit EU data for an NDA filing



## **Cystinuria: a rare and well documented genetic disease**

- **Cystinuria** is a rare genetic disease characterized by a build-up of undissolved cystine in the kidneys and bladder, leading to the formation of cystine crystals and/or stones which may block the urinary tract
- Cystine stones are challenging and often require expensive, invasive surgical removal
- Cystinuria often leads to chronic kidney disease (CKD), nephrectomy, kidney atrophy, recurrent urinary tract infections and hypertension
- Estimated prevalence of c.40,000 cases in Europe/UK, c.30,000 cases in the US
- US ICD-10 code for easier diagnosis and reimbursement processes



## **Advicenne Regulatory Strategy for Cystinuria**



Advicenne strategy in cystinuria validated by grant of ODD

#### Importance of achieving ODD

- > Implicit agreement from FDA that this drug has a role in cystinuria plausibility
- > Opens door to discuss PIII registration study with urine pH primary endpoint

#### FDA strategy in cystinuria

- > Ready to execute plan to agree study design for PIII in cystinuria
- Secure PIII registration study design with urinary pH as primary endpoint via Type C Meeting, leveraging patient advocates and global experts
- > Type C meeting to be held in Q4 2024



#### H1 2024 P&L – current / non current

EMENT euros)	June 30, 2024	June 30, 2023	Variance
Revenues	1 658	1 581	77
Income from partnerships	119	4	115
Other operating income	137	138	-2
Total revenue and other income	1 914	1 723	190
Cost of goods sold current	-1 035	-570	-465
Research and development expenses current	-1 759	-1 947	188
Sales and marketing expenses current	-603	-510	-93
Overhead and general expenses current	-1 360	-1 641	281
		-	
Current operating income	-2 843	-2 945	102
	-33		
Cost of goods sold non current Research and development expenses non current	-33	-	
Research and development expenses non current	-1 004	-	
Non current operating items	-1 836	-	-1 836
		-	
Operating income	-4 679	-2 945	-1 735
Net financing costs	-880	-781	-99
Other financial expenses	-8	-20	12
Other financial income	28	12	16
Income before taxes	-5 539	-3 733	-1 806
Income taxes	6	-0	6
Consolidated net profit / loss	-5 533	-3 734	-1 799
Earnings per share (€/share)	- 0,45	- 0,38	- 0.07
Diluted earnings per share (€/share)	- 0,45	- 0,38	- 0.07
	0,40	0,50	0,07

• **Gross sales:** 2,462 KEUR, up +10%

- Sibnayal® up 14%, incl. royalties.
- Sibnayal® in France up 40%;
- c. 10 new patients per month
- Current Operating losses: 2.8 MEUR vs 2.9
   MEUR
  - CoGS: up on inventory impact in H1 2024
  - R&D: mainly to support ADV7103 US development (dRTA & cystinuria)
  - S&M (+18%): focused on commercial efforts on Sibnayal® in Europe
  - G&A down 17% vs H1 2023: tight management of expenses

## June 30, 2024 - Cashflow statement IFRS

	June 30, 2024	June 30, 2023
ıros)		
Net result (loss)	-5 533	-3 734
Amortisation, depreciation and provisions	1 659	102
Share-based payments	79	164
Net financial costs	712	627
Sale of PPE and intangible assets	9	-
Self-financing capacity	-3 074	-2 841
Changes in inventory	19	-686
Changes in trade and other receivables	-499	-238
Changes in trade and other payables	907	55
Cash flow from operations	-2 647	-3 709
Acquisition of PPE and intangible assets	-35	-625
Sale of financial assets	-	2
Cash flow from investing activities	-35	-623
Own shares held in treasury	-4	-28
Repayment of borrowings and refundable advances	-596	-540
Cash flow from financing activities	-600	-568
Changes in value of local currencies	-	-4
Change in cash	-3 282	-4 905
Opening cash position	5 250	8 322
Closing cash position	1 968	3 417

## H1 2024 Net cashburn: 3.3 MEUR vs 4.9 MEUR in H1 2023

#### Cashflow from operations

- Sustained improvement to -2.6 MEUR vs -3,7 MEUR in H1 2023.
- Directly linked to revenue increase and cost control
- Impairment of stickpack: non cash

#### Cashflow from investing activities

Close to zero

• in 2023, stickpack payment

#### Cashflow from financing activities

Reimbursement of PGE

#### Cash runway: Q1 2025

## Advicenne's value proposition



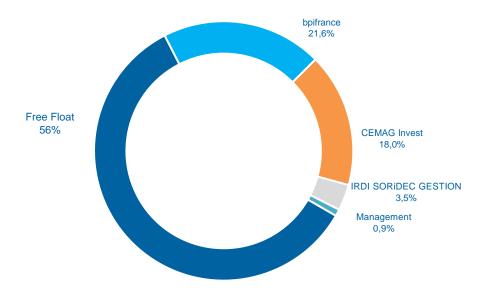
- European organization
- Operating platform in France and the UK
- Rare diseases expertise
- Sibnayal<sup>®</sup> (ADV7103) dRTA commercial status with full European coverage through distribution agreements
- Phase III studies agreed upon with EMA in Cystinuria



- US footprint
- ADV7103 Orphan Drug Designation in dRTA and cystinuria
- Low clinical risk / Pediatric indication / formulation
- Significant US market potential in two orphan indications
- Potential extended IP protection beyond currently 2031
- Regulatory clarity for NDA



### **Shareholding structure**



Source: Company information



## advicenne

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