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THERAPEUTICS

PatchPump®: Making Good Drugs Better

PDA Universe of Pre-Filled Syringes and Injection Devices
November 2015
Vienna, Austria

Notice Regarding Forward-Looking Statements

This presentation and the accompanying oral commentary contain both historical and forward-looking statements which are based on current expectations, estimates and projections. Statements that are not historical facts are forward-looking statements and typically are identified by words like “may,” “believe,” “anticipate,” “could,” “should,” “estimate,” “expect,” “intend,” “plan,” “project,” “will,” “forecast,” “approximately,” “budget,” “pro forma”, or the negative of these terms or other words that convey uncertainty of future events or outcomes to identify these forward-looking statements. All statements other than statements of historical facts contained in this presentation and the accompanying oral commentary are forward-looking statements, and include statements regarding our intentions, beliefs, projections, outlook, analyses or current expectations concerning, among other things: the development of Trevyent and our At Home Patient Analgesia product candidates, the regulatory pathways for potential marketing approval of our product candidates, our intellectual property position, the market opportunities for our product candidates and our cash position.

Forward-looking statements involve known and unknown risks, uncertainties, assumptions and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements. We discuss many of these risks in greater detail under the heading "Risk Factors" contained in our Quarterly Report on Form 10-Q ending the period June 30, 2015 which is on file with the Securities and Exchange Commission. Forward-looking statements are not guarantees of future performance and our actual results of operations, financial condition and liquidity, and the development of the industry in which we operate may differ materially from the forward-looking statements contained in this presentation and the accompanying oral commentary. Any forward-looking statements that we make in this presentation and the accompanying oral commentary speak only as of the date of this presentation. We assume no obligation to update our forward-looking statements whether as a result of new information, future events or otherwise.

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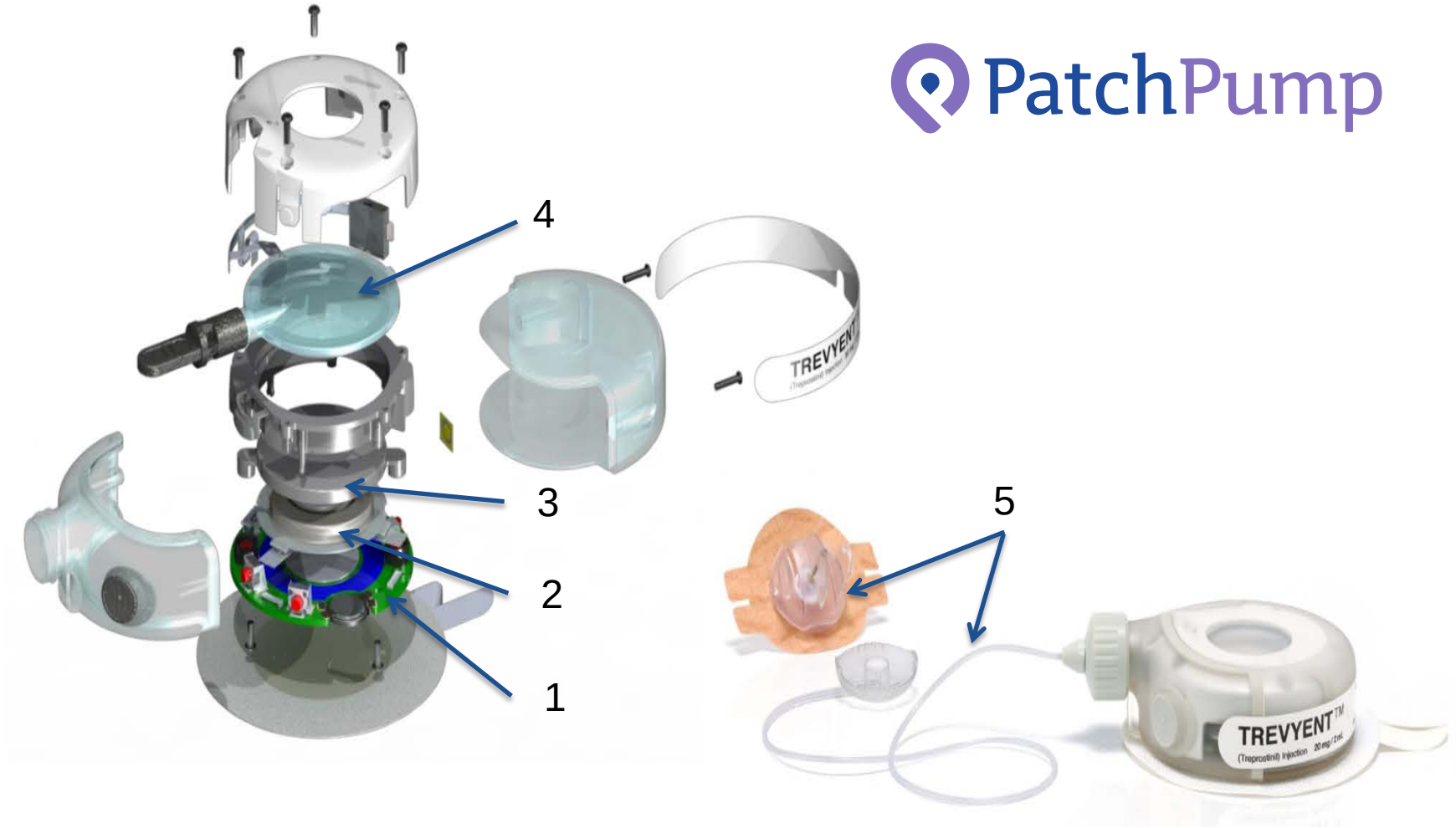
PatchPump



1. **PCB** – controls delivery rate and dose, sensors provide visible and audible feedback to patient
2. **ECell** – an expanding battery that acts as the ‘motor’ in the PatchPump to drive the piston
3. **Piston** – compresses the collapsible drug container to deliver drug through a soft cannula
4. **Drug container** – aseptically filled with sterile liquid drug at site of manufacture
5. **Infusion Set** – delivers drug subcutaneously or intravenously

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Our Primary Target – Pulmonary Arterial Hypertension

- **Progressive, life changing and life-threatening disease**
- **Orphan indication with ~30,000 patients diagnosed in the U.S.**
- **Fewer than 200 treatment centers in the U.S.**
- **Remodulin (treprostinil - United Therapeutics) is the market leading prostacyclin therapy**

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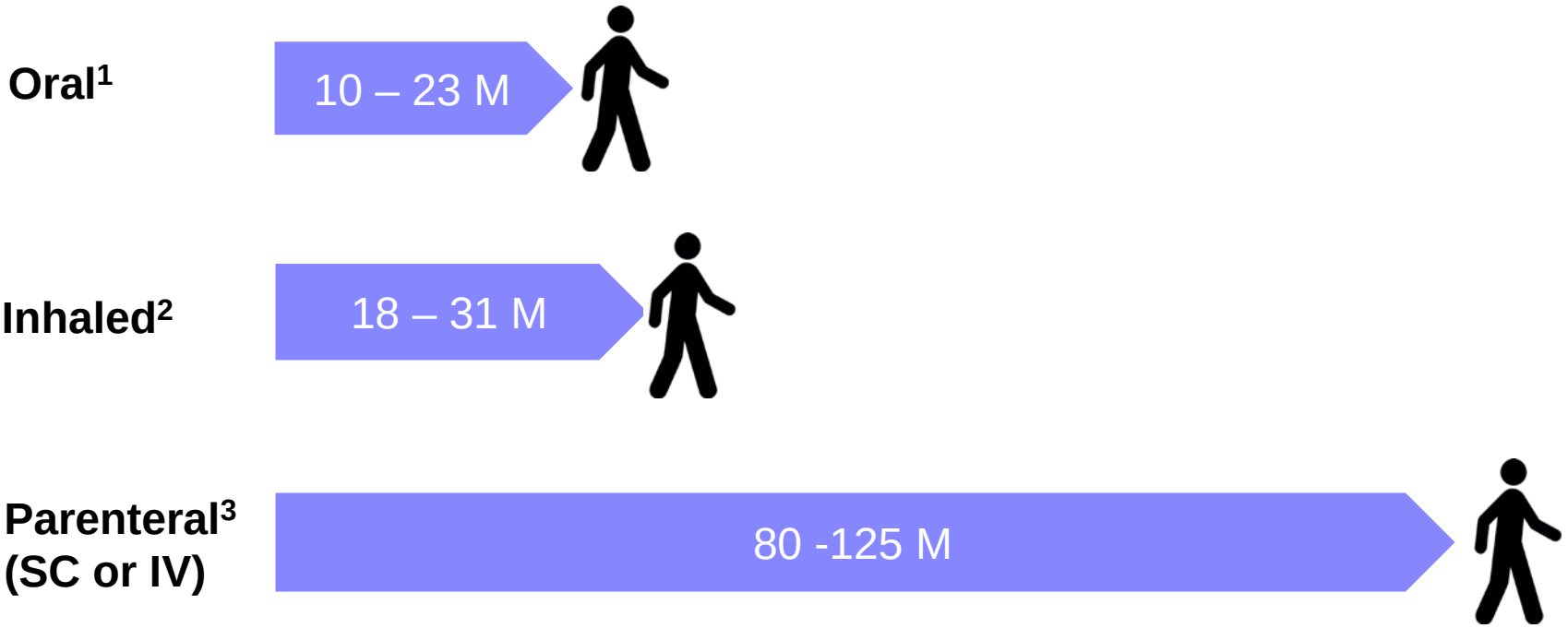
Administration System Limitations of Remodulin

- **Pumps not designed for PAH or treprostinil**
- **Complex programming and error prone filling**
  - Infusion system complications in 28% of patients in controlled clinical studies
- **Subcutaneous Infusion site pain in 85% of patients**
  - May be linked to meta-cresol preservative
- **IV pump reservoir requires drug dilution**
  - Incorrect dosing possible
  - Poor aseptic technique can cause blood stream infection (BSI) and sepsis
- **Not water resistant**
- **Back-up pump needed**

Parenteral Treprostinil is the Most Efficacious

6-Minute Walk test data. Improvement from baseline in meters (M) walked.



1; Tapson et al., 2012; Jing et al., 2013; Tapson et al., 2013
2; McLaughlin et al., 2010. Benza et al., 2011
3; Tapson et al (2006). Hiremath et al (2010). Benza et al., 2013

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Addressing the Limitations of Existing Therapy

- **Convenient and ready-to-go**
  - No patient filling; aseptically pre-filled with treprostinil
  - 48 hour duration before disposal and replacement
- **Simple dosing with no programming**
  - Pre-programmed at site of manufacture
  - No dosing buttons prevents tampering or accidental bolus
- **For SC and IV therapy**
  - No need for diluents
- **Preservative free**
  - May reduce SC infusion site pain seen with Remodulin
- **Compact and water resistant**

Trevyent
TREPROSTINIL SODIUM

Comparable dosing profile for treprostinil

PK parameter	PatchPump mean (SD)	Wade, 2004 mean (SD)	Laliberte, 2004 mean (SD)
C_{ss} (pg/mL)	297 (84)	259 (42)	–
$T_{1/2}$ (hrs)	4.44 (2.72)	2.931 (0.746)	4.6 (2.72)

- PatchPump data from early-prototype POC PK study (Shaked et al., *Pharm Res*, 2015)
- Key PK parameters comparable to Remodulin literature

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Patients are Looking for Better Treatment Options

- **May 2014, "Voice of the Patient" meeting with FDA & 85 PAH patients**
- **Key discussion topics:**
  - The impact of PAH on daily life & currently available therapies
- **Summary of major themes:**
  - PAH is a progressive, devastating disease
  - PAH negatively affects all aspects of patients' lives
  - Nearly all participants described using combination therapy
  - And…

Patients emphasized the need for medications that are effective, have ***convenient dosing schedules*** *and are* ***easy and safe to administer***

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Trevyent Usability Validated with PAH Patients

Study	Complete	Goal	Study	Complete	Goal
1	☐	Ethnographic research	5	☐	Full simulated use
2	☐	User interface evaluation	6	☐	User interface evaluation
3	☐	User interface evaluation	7	☐	Full simulated use
4	☐	Wearability preferences	8	☐	Final Validation

- **2 year program of 8 Human Factors studies completed**
- **Goal – Design Trevyent specifically for treprostinil and for patients with PAH**
  - Refine Trevyent design in an iterative manner to identify and mitigate safety issues and validate usability
  - **148** subjects in U.S. and Europe - **92** PAH patients, **33** PAH Physicians, **23** other
  - Met with CDRH* and DMEPA* in November 2014 to review HF program
  - Usability of Trevyent validated

 * Center for Devices and Radiological Health (CDRH), Division of Medical Error Prevention and Analysis (DMEPA)

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Low Risk Regulatory Pathway – Bio-waiver Confirmed

- **Bio-waiver confirmed – No clinical studies required for approval**
  - 505(b)(2) NDA in the United States – confirmed with CDER, CDRH and DMEPA
  - Hybrid 10(3) Application in the E.U. – confirmed with UK, Germany and Sweden
- **NDA submission anticipated Q3 2016 and E.U. MAA H2 2016**
- **Remodulin safety and efficacy data to be included in Trevyent prescribing information**
- **Numerous examples of FDA product approvals through bio-waiver**
  - Parenteral epoprostenol reformulation (Veletri®, Actelion) for PAH

"FDA shall waive the requirement for clinical studies if the new drug product is a parenteral injection and it contains the same active and inactive ingredients in the same concentration as a previously approved drug."

FDA regulation 21 CFR 320.22(b)

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Treyvent

TREPROSTINIL SODIUM

For Patients

- Convenient, ready-to-go
- Simple dosing with predictable 48 hour period
- Discreet
- Compact and water resistant
- Offers patient reassurance

For Physicians and Caregivers

- Eliminates manual re-filling
- Reduces dosing errors
- Less training time required
- Aseptically filled at the site of manufacture

For Payors

- Lower annual cost of therapy
- Equivalent drug cost to Remodulin (~$150k annually)
- Unlike Remodulin – No additional cost for pumps, diluents, infusion sets, or other medical supplies

Post-Surgical Pain – A Significant Unmet Opportunity

- **>70 million surgeries performed annually in the U.S.**
- **~75% of patients experience inadequate pain relief**
- **Limitations of current at home pain treatments**
  - Poor side effect profile, risk of abuse (opioids)
  - Inconvenient dosing (IV or IM NSAIDs)
  - Bulky elastomeric pumps with associated dosing inaccuracies and pharmacy compounding
  - Long-acting bupivacaine provides only 24 hours of pain relief (Exparel®)
- **Goal – Reduce the length of hospital stay and treat patients at home with effective and well tolerated therapy**

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At Home Patient Analgesia (AHPA)

Bupivacaine AHPA

- Local surgical wound analgesia
- No pharmacy compounding
- Reduced length of hospital stay
- Can be used for multiple days
- Reduces need for oral narcotics

Ketorolac AHPA

- Continuous subcutaneous delivery eliminates IV/IM initiation
- Around-the-clock potent pain relief for up to five days
- Avoids respiratory depression and side effects linked to opioids
- PK study comparing continuous SC vs IV completed Q3-2015

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Summary - Late-Stage Specialty Pharmaceutical Company

Trevyent® for pulmonary arterial hypertension (PAH)

- Treprostinil and PatchPump combination
- Overcomes limitations of market leader Remodulin® (treprostinil)
- File NDA Q3 2016
- SteadyMed to commercialize in U.S.
- Licensed to Cardiome for Europe, Canada and Middle East
- File MAA H2 2016
- High revenue, high margin ~$150,000 per patient per year

Pipeline of two At-Home Patient Analgesia (AHPA) product candidates

- Ketorolac and Bupivacaine
- SMT – 201 (Ketorolac) Pharmacokinetic Proof of Concept study completed Q3-2015

PatchPump platform technology with broad applications

NASDAQ listed March 2015, (STDY)

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Thank You!