INTERNATIONAL WORKSHOP ON MEDICAL RADIOISOTOPES SUPPLY

Current Regulatory Challenges for Radiopharmaceutical Companies

Roy W. Brown
V.P., Govt. Affairs & Strategic Alliances
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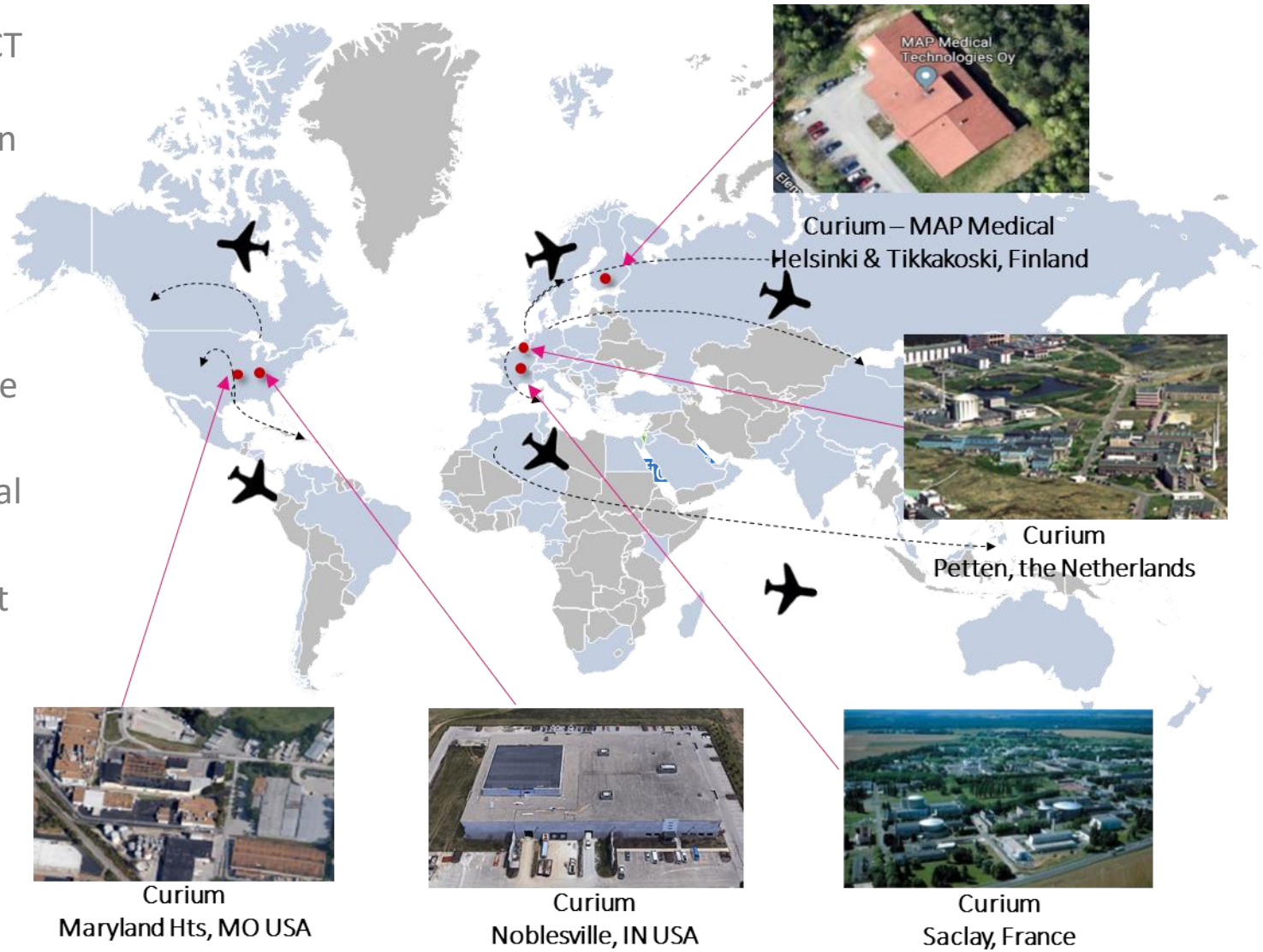
Overview of Curium's Operations

- Molybdenum (Mo-99) facility in Petten makes Curium the only global vertically integrated SPECT manufacturer.
  - Very high reliability for the key isotope used in approximately 85% of all nuclear medicine procedures.
- Delivering SPECT products to >60 countries worldwide with 50+ products in our portfolio.
- 55 SPECT and PET radiopharmacies across Europe dispensing unit doses.
- Curium is completing a new Lu-177 radiochemical production lab in our Petten facility.
- Curium is completing a Lu-177 labelling facility at our Noblesville facility.
- The ECLIPSE Trial is currently recruiting patients with mCRPC who may be eligible for enrollment in this clinical trial of Lu-177 PSMA-I&T.
- The SOLAR Cu-64 PSMA I&T Trial Ph1/2 is complete, and we anticipate activation of Ph3 Trials in Q1 2024.



Key Global Regulatory Concerns

- In the EU once EMA MA is achieved, after showing safety & efficacy, you must still get individual country approvals, delaying patent access to approved drugs.
- Drug regulatory agency work sharing programs are working, but further utilization may reduce regulatory burden and decrease approval times.
- NMEU & EANM have been working with the EU in their rewrite of existing medicines legislation.
- Reimbursement inequity has a negative impact on patient access
  - Inconsistent reimbursement is common across EU states.
  - The industry in the U.S. has been pushing the FIND Act to “unbundle” payments.
- European Compassionate Use has made life-changing products available to patients.
  - The use of RWE or RWD as a tool to gather clinical knowledge of new radiopharmaceutical agents to aid in decision making and product development
- On what level is it possible to use non-GMP material due to rare availability, and are there analytical assessments that can adequately ensure their safe use