Towards a malaria-free world

Medicines for Malaria Venture (MMV) and partners discover, develop and deliver new, effective and affordable antimalarials to give populations at risk a better chance to achieve good health and wellbeing.

Accelerating progress towards malaria elimination is the objective of the entire malaria community. MMV’s focus is to work with partners to provide access to quality antimalarials while developing new medicines that will fulfill unmet needs and address future challenges, such as drug resistance.

Within the broader context of rising antimicrobial resistance, drug resistant malaria has emerged in Southeast Asia and markers of partial resistance have been reported in Rwanda. If resistance to antimalarial medicines were to take hold in sub-Saharan Africa, where the malaria burden is highest, it would pose a major threat to malaria control and elimination efforts. MMV is working to bring forward next-generation antimalarials to address this perpetual threat. Further, the COVID-19 pandemic has brought additional challenges, placing a burden on healthcare systems as well as supply of scarce resources. MMV is working to adapt to this evolving context.

Our antimalarial portfolio (see p. 3) is the largest ever assembled and comprises 13 compounds in clinical development targeting unmet medical needs, including medicines for children, pregnant women and people suffering from drug-resistant malaria. These antimalarials hold the promise of contributing to the global drive towards malaria eradication as well as Sustainable Development Goal 3 to achieve good health and wellbeing for all.

MMV-supported medicines

- **Coartem® Dispersible** (artemether-lumefantrine), a child-friendly formulation developed with Novartis for treatment of uncomplicated malaria
- **Injectable artesunate**, Fosun Pharma and Ipca’s products for treatment of severe malaria
- **Eurartesim®** (dihydroartemisinin-piperaquine), developed with Alfasigma for treatment of uncomplicated malaria
- **Pyramax® tablets** (pyronaridine-artesunate), Shin Poong’s product for treatment of uncomplicated malaria
- **Pyramax® granules**, a child-friendly formulation of Pyramax
- **SP+AQ** (sulfadoxine-pyrimethamine + amodiaquine products for seasonal malaria chemoprevention in children
- **ASAQ Winthrop®** (artesunate-amodiaquine), developed by Sanofi with DNDi, transferred from DNDi to MMV to support improved access
- **Artesunate rectal capsules**, Cipla’s and Strides Shasun’s products for pre-referral management of severe malaria in children
- **ASMQ** (artesunate-mefloquine), developed by Farmanguinhos, DNDi and Cipla, transferred from DNDi to MMV to support improved access
- **Krintafel/Kozenis®** (tafenoquine), a single-dose cure for relapsing malaria developed with GSK

Defeating Malaria Together
MMV’s Product Development Partnership (PDP) continues to bear fruit. Combining the technical skills of our network of partners from industry and academia with our in-house expertise, MMV remains a highly productive and cost-effective research and development organization.

Each partner brings technical know-how, enabling technologies, research facilities and funding. MMV brings a wealth of malaria and R&D knowledge together with industry-style portfolio management. Our Target Product Profiles and Target Candidate Profiles (see p. 3) provide a clear framework for research and development. With this in mind, support is provided for the most promising drug candidates, while those that do not meet the target profile are quickly terminated. This rigorous candidate selection and management enables us to maximize value while accelerating the progress of compounds through the pipeline.

To keep the development costs as low as possible, MMV benchmarks costs and follows a robust procurement process when engaging with research service providers. We also aim to contain production costs by working with our partners to seek the most efficient routes of synthesis for our medicines—beyond reductions expected from economies of scale.

In this way, MMV is able to maximize the value of every donor dollar to our highly focused mission and develop high-quality medicines that are affordable for vulnerable populations.
## MMV-supported projects

Antimalarial drug discovery and development projects scientifically and/or financially supported by MMV.

### Research

<table>
<thead>
<tr>
<th>Lead optimization</th>
<th>Candidate profiling</th>
<th>Preclinical</th>
<th>Human volunteers</th>
<th>Patient exploratory</th>
<th>Patient confirmatory</th>
<th>Regulatory review</th>
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<tr>
<td>Miniportfolio GSK</td>
<td>SJ73 backup Univ. of Kentucky</td>
<td>MMV1581373 Novartis</td>
<td>MMV533 (Sanofi)</td>
<td>P218 Jannsen</td>
<td>Artefenome/ferroquine Novartis</td>
<td>Dihydro-artemisinin-piperazine dispersible Alfasigma</td>
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<td>Phenotypic lead</td>
<td>Mitsubishi Tanaba</td>
<td>Molecular target</td>
<td>UC8</td>
<td>MMV370 MMV371 Janssen</td>
<td>Ganapalide/lumefantrine Novartis</td>
<td>Tafenoquine paediatric GSK</td>
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<td>Univ. of Sydney</td>
<td>DHODH</td>
<td>Broad Institute</td>
<td>MMV183 (TropIQ)</td>
<td>Ciparagamin Novartis</td>
<td>Sulfadoxine-pyrimethamine Universal Corporation</td>
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<td>Purines Celsense</td>
<td>DHODH</td>
<td>Molecular target</td>
<td>Southwestern/Univ. of Washington/ Monash Univ.</td>
<td>MMV253 Zydus Cadila</td>
<td>DSM265 Takeda</td>
<td>Arteether-lumefantrine &lt; 5 kg Novartis</td>
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<td>GWT1 Eisai</td>
<td>Phenotypic lead</td>
<td>Merck KGaA</td>
<td>Univ. of Cape Town</td>
<td>MMV646 (Jacobus)</td>
<td>Artesunate ipca</td>
<td>Artesunate rectal capsules Cipla</td>
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<td>Drug Discovery Unit Univ. of Dundee</td>
<td>Intra-muscular</td>
<td>Calibr</td>
<td>INE963 Novartis</td>
<td>MMV048 (Univ. of Cape Town)</td>
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<td>Azabenzimidazole UNICAMP, Univ. of Campinas</td>
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<tr>
<td>Miniportfolio Novartis</td>
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### Translational

- **3-day cure, artemisinin-based combination therapies (TPP1)**
- **Uncomplicated malaria treatments for single-exposure radical cure (SERC) and/or resistance management (TPP1)**
- **Intermittent preventive treatment (TPP1)**
- **Severe malaria treatment/pre-referral intervention (TPP1)**
- **Products targeting prevention of relapse for P. vivax (TPP1)**
- **Prophylaxis (TPP2)**

### Product development

- **Artemether-lumefantrine dispersible Novartis**
- **Artesunate for injection Fosun Pharma**
- **Sulfadoxine-pyrimethamine + amodiaquine dispersible Fosun Pharma**
- **Artesunate for injection Ipca**
- **Sulfadoxine-pyrimethamine + amodiaquine dispersible**
- **Artesunate rectal capsules Cipla**
- **Dihydro-artemisinin-piperaquine Alfasigma**
- **Artesunate rectal capsules Strides Pharma**
- **Artesunate-arnesunate granules Shin Poong**
- **Artesunate-amodiaquine Sanofi**
- **Tafenoquine GSK**

### Access

- **Approved/ERP**
  - MMV at a Glance 2020 | www.mmv.org

### Candidate profiles

- **Brand names:** 1. Coartem® Dispersible; 2. Artesun®; 3. Larinate® 60mg; 4. Eurartesim®; 5. Pyramax® tablets or granules; 6. ASAQ Winthrop®; 7. SPAQ-CD®; 8. Supyra®; 9. 100 mg Artesunate Rectocaps; 10. Artecap®; 11. Krintafel/Kozenis (Trademarks owned or licensed by GSK)

### Target product profiles

1. **3-day cure, artemisinin-based combination therapies (TPP1)**
2. **Uncomplicated malaria treatments for single-exposure radical cure (SERC) and/or resistance management (TPP1)**
3. **Intermittent preventive treatment (TPP1)**
4. **Severe malaria treatment/pre-referral intervention (TPP1)**
5. **Products targeting prevention of relapse for P. vivax (TPP1)**
6. **Prophylaxis (TPP2)**

### GOVERNANCE

- **ESAC** Expert Scientific Advisory Committee
- **GSB** Global Safety Board
- **APAC** Authorization for Phase II/Advancement Committee
- **APM** Access and Product Management Advisory Committee

### MMV Board of Directors/Executive Committee/Financial Audit Committee

#### Target product profiles

- **Asexual blood stages** (TCP 1)
- **Relapse prevention** (TCP 3)
- **Causal prophylaxis** (TCP 4)
- **Transmission reduction** (TCP 5, 6)

#### To develop the individual compounds for combination into the TPPs, MMV has defined five target candidate profiles (TCPs):

- **Included in MMV portfolio after product approval and/or development**
- **Global Fund Expert Review Panel reviewed product – permitted for time-limited procurement, while regulatory/WHO prequalification review is ongoing**
- **Paediatric formulation**
- **WHO prequalified OR approved/positive opinion by regulatory bodies who are ICH* members/observers**
- **Via a bioequivalence study**

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* International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use
Since its inception in 1999, MMV has successfully worked in over 50 countries with more than 400 partners from:
- the public and private sectors
- NGOs and non-profit organizations
- clinical trial sites

Today, around 150 active partners are working on MMV projects in 30 countries.

More than 400 partners

...over 50 countries

The road to health impact

Discovering and developing new lifesaving antimalarials are not enough to ensure patient impact, which is why MMV is also committed to delivering these medicines to those most in need. There are numerous barriers to creating access to medicines; here is how we work to overcome some of them.

The circle of access to the right shows key hurdles that must be addressed as laboratory-developed drugs are transformed into life-saving medicines that can have massive impact.

As a first step, it is critical that medicines brought to market have demonstrated their efficacy and safety both to Stringent Regulatory Authorities (SRAs) as well as to WHO Prequalification. National regulators must also be assured that new medicines will be tracked for safety in “real-life” settings. This pharmacovigilance expands knowledge about product safety after launch. Crucial to catalyzing the uptake of medicines after in-country registration is their inclusion in national treatment protocols. The Standard Treatment Guidelines from WHO’s Global Malaria Programme (GMP) provide global guidance to countries in this regard. MMV supports provision of all requisite evidence for formulation of recommendations.

Both during product development and after launch, MMV works carefully with national research partners to ensure that key aspects of product acceptance facilitate adoption—this work can include palatability testing of medicines designed for children or refinement of product packaging and instructions for caregivers. Similarly, we focus closely on developing training materials and programmes to ensure healthcare professionals will readily understand how to safely and effectively administer new medicines.

The roles of both the public and private sectors are central to ensuring global access to antimalarial medicines. An imperative to understand the market and how these actors interact drives our commitment to invest in both quantitative and qualitative market research. In addition, linking our pharma partners with market demand forecasts helps ensure that there is advanced visibility for industry to prepare for evolving demand for their products.

Lastly, as new medicines become more widely adopted, we carefully consider the international financing of new medicines for lower income countries, as well as the need to ensure that global supplies will be adequate. MMV supports financing and procurement institutions to ensure that all pertinent data about the affordability, availability, and unique attributes of new products are clearly communicated to decision makers. This helps to make quality medicines available for procurement where they are most needed.

Today, an estimated 405,000 people still die from malaria every year. By developing next-generation medicines and increasing the accessibility of those which are already available, we are working with partners in pursuit of a future where no one will suffer or die from malaria.
Focus on finances

Medicines for Malaria Venture receives sustained funding and support from government agencies, private foundations, international organizations, corporations, corporate foundations and private individuals. These funds are used to finance MMV’s portfolio of R&D projects as well as specific, targeted access and delivery interventions that aim to make it easier for vulnerable populations to access MMV products.

Since its foundation in 1999, MMV has established the world’s largest R&D portfolio of new and innovative antimalarial medicines. With partners, MMV has brought forward eleven new antimalarials and taken over the access stewardship of two more. Together, these medicines have saved an estimated 2.2 million lives. Our 2017-2021 business plan estimates the need for a minimum of USD 340 million over the period 2018–2021 to sustain progress in research is dependent on funding. With approximately USD 325 million available at the end of 2019 (USD 57.2 million cash, plus USD 252 million committed pledges over the period 2020–2024, plus a residual USD 15.6 million receivable from pharmaceutical partner GSK), the organization is currently tracking a project-budget gap of approximately USD 100 million over the period 2022-2024. To overcome this, we are striving to expand and develop current and new donor relationships and negotiate the best terms with our partners.

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**Figure 1** Total donations received/pledged 1999–2024

<table>
<thead>
<tr>
<th>Organization</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bill &amp; Melinda Gates Foundation</td>
<td>57.26%</td>
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<tr>
<td>United Kingdom (Department for International Development (DFID) and the Department of Health)</td>
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<td>US Government (United States Agency for International Development (USAID; 2.9%)/National Institutes of Health (NIH; 0.9%))</td>
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<tr>
<td>Netherlands Ministry for Development Cooperation (OTA)</td>
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<tr>
<td>Welcome Trust</td>
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<tr>
<td>Swiss Agency for Development and Cooperation (SDC)</td>
<td>2.16%</td>
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<tr>
<td>Australian Government Department of Foreign Affairs and Trade (DFAT)</td>
<td>2.05%</td>
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<tr>
<td>European and Developing Countries Clinical Trials Partnership (EDCTP)</td>
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<td>Unitaid</td>
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<td>Malaria Consortium</td>
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<td>Johnson &amp; Johnson Corporate Citizenship Trust</td>
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<td>BHP Billiton</td>
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<td>Individual donors</td>
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<tr>
<td>Direction de la Coopération Internationale, Principauté de Monaco (DCI)</td>
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<td>CRIMALDDI Consortium</td>
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</tr>
</tbody>
</table>

**Figure 2** MMV expenditure 2019 Total: USD 96.6 million

- Research & development: 69%
- Access & product management: 16%
- Administration & finance: 6%
- Corporate affairs: 6%
- Other portfolio expenditure: 3%

### Board of Directors

Mr Per Wold-Olsen (Chairman), Dr David Brandling-Bennett, Mr Alan Court, Prof Sir Michael Ferguson, Dr Winston Gutteridge, Mr Gabriel Jaramillo, Ms Yuli Ismartono, Dr David Reddy, Dr Wendy Sanhai, Ms Elizabeth Linder, Mr Robert Newman, Ms Joy Phumphi, Dr David Reddy, Dr Wendy Sanhai, Ambassador Dr Koji Sebati and Dr Dennis Schmatz.

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Editors: Danielle Sessa and Elizabeth Poll
Photos: Toby Madden/MMV (cover & p 6a), Elizabeth Poll (p 6b) and Damien Schumann (p 6c)

Designer: ComStone-Pierre Chassany
Key achievements

**150 million vials of injectable artemisinin**
distributed by MMV-supported manufacturers Fosun Pharma and Ipca, saving around 950,000 additional lives when compared to treatment with quinine.

**Over 390 million treatments of child-friendly Coartem® Dispersible**
(artemether-lumefantrine, co-developed with Novartis) distributed in more than 50 countries since launch in 2009.

**Over 300 Pathogen Boxes shipped free of charge to scientists**
around the world to boost neglected diseases drug discovery.

**More than 2.2 million lives saved**
by MMV-supported medicines since 2009.

**First child-friendly medicine approved via article 58. Pyramax® Granules**
(pyronaridine-artesunate, co-developed with Shin Poong) received EMA positive scientific opinion in Nov 2015. Added to the WHO List of Prequalified Medicinal Products in 2016 and to its Model List of Essential Medicines in 2017.

**First single dose cure for relapsing malaria**
(tafenoquine) approved in two malaria-endemic countries, Brazil and Thailand.

**Over 357 million courses of SP+AQ**
shipped to countries in Africa’s Sahel region since 2014 by MMV-supported manufacturers S. Kanto and Fosun Pharma. In 2019 alone the intervention has protected an estimated over 20 million children.