Access to CML Treatment in LMIC

Pat Garcia-Gonzalez, May 2019
ACCESS TO TREATMENT
understanding the universe

HOW DID WE GET HERE
transition from GIPAP to MAS

WHAT HAVE WE ACHIEVED
good, bad and ugly
As advocates our job is to look outside of the circle. The universe of people that need our help is infinite.
Access to TKIs, historical perspective

- **Glivec Approval**
  - 2001
  - 80 countries
  - 75,000 patients
  - 15 years

- **Some access to Tasigna through NOA**
  - 2007

- **Max Access Solutions Launches Iclusig, Sprycel**
  - 2016

- **Iclusig, Sprycel, Glivec, Tasigna**
  - 2017

- **Max Access Solutions**
  - 2018
  - Iclusig, Sprycel, Glivec, Tasigna, Bosulif
Number of Patients on CML Treatment as of May 1, 2019

<table>
<thead>
<tr>
<th>MAX ACCESS SOLUTIONS</th>
<th>PATIENT ACCESS PROGRAMS (MAX)</th>
<th>PATIENT ACCESS PROGRAMS (OTHER)</th>
</tr>
</thead>
<tbody>
<tr>
<td>GLIVEC 13,753</td>
<td>GLIVEC 21,244</td>
<td>GLIVEC 27,000+</td>
</tr>
<tr>
<td>TASIGNA 268</td>
<td>TASIGNA 715</td>
<td>TASIGNA 10,000</td>
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<tr>
<td>SPRYCELI 329</td>
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<td>SPRYCELI</td>
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<tr>
<td>BOSULIF 80</td>
<td>ICLUSIG 220</td>
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Over 73,000+ CML patients supported by access programs in low- and middle-income countries!
MAS active cases on 2nd line treatment

- **Sprycel, 329**
- **Tasigna, 268**
- **Iclusig, 220**
- **Bosulif, 80**

Number of patients

- July-2018 to April-2019
The Good, The Bad and The Ugly

2019 Access to treatment for CML in LMIC
The Ugly
## The Ugly in 2019

<table>
<thead>
<tr>
<th>Country</th>
<th>Issue 描述</th>
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</table>
| **India** | 1. Delayed transition to MAS due to import taxes  
            2. No commercial Bosulif or Iclusig  
            3. Cumbersome regulatory process for humanitarian access |
| **Malaysia** | 1. Waiting list for patients to access first line treatment  
                  2. No commercial Sprycel, Bosulif or Iclusig |
| **Philippines** | 1. Month supply of Glivec over $3,000 USD  
                              2. High import taxes  
                              3. Patients accessing black market through web |
The Bad
The most pervasive barrier to achieving optimal clinical outcomes in CML in LMIC in 2019 is lack of access to PCR
The 5-Year Gap in PCR

- Fixed costs: $1.9 million
- Variable costs: $27.2 million

Resources needed for monitoring the treatment of our CML patients in the next 5 years is $29 million dollars
Spot On CML

- Developed by Dr. Radich
- Extract RNA from dry blood spot to estimate PCR levels
- Over 15 countries participated, including Mexico and The Philippines.
Solidarity Fund
Provides sustained access to PCR tests for all patients

2018
Bolivia
Cambodia
Haiti
Honduras
Kyrgyzstan
Papua New Guinea
Timor Leste

2019
Rwanda (PIH)
Tajikistan
Uganda
Nicaragua
Malawi
The Good
Overall Survival of CML Patients in GIPAP

63,000 GIPAP patients in 93 countries received over 71 million defined daily doses (DDD) of imatinib between 2001 and 2014.

Umeh, et al. submitted 2019
The Good in 2019

THAILAND

GIPAP since 2003 helped 6,000+ patients

2019, patent expiration: government takes over the treatment of all patients
The Good in 2019

VENEZUELA

- GIPAP in the early 2000’s
- Government takes over access to treatment and provides all TKIs
- Crisis: 1,500 patients without treatment
- 2018 Novartis agrees to include in MAS
- 2018 Glivec available in the country for CML patients
The Good in 2019

KYRGYZSTAN

Located in Central Asia, Capital is Bishkek

Cancer center: The National Center of Oncology

189 patients transitioned from GIPAP to MAS in 2017
Contribute to the Good
Improve the Bad
Change the Ugly
I would like to acknowledge the following individuals:

• Our Programs team: Local Program Coordinators, Program Officers, Senior Program Managers, Supply Chain managers, Admin team

• Our distribution partners in Tanner Pharma

• Our donor partners: Novartis, BMS, Takeda, Pfizer and Incyte

• Our Implementing partner physicians, patient organizations, Ministries of Health, Cepheid

• Our patients and their families

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