























FMF /N2301 




    















1. /N2301 ⁵









1  2 


 
 colchicine resistant Familial Mediterranean Fever (crFMF) 
 150mg 4 

 
 63

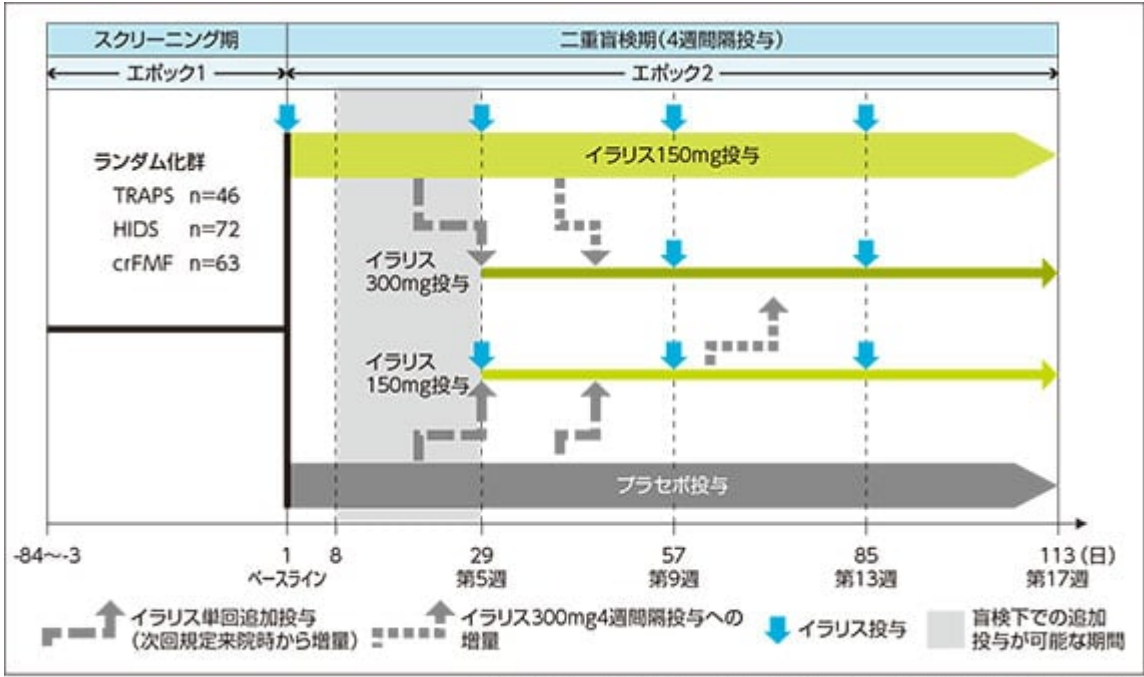
 
 150mg  2mg/kg  1  1  4 


- 7  28  :  150mg  2mg/kg  1  29 
- 29  :  → 150mg → 300mg  300mg 
 4mg/kg  4 

 40kg  150mg  300mg  40kg  2mg/kg 
 4mg/kg 



Image



5) 社内資料：TRAPS/HIDS/crFMFにおける国際共同第III相試験(N2301)(承認時評価資料)

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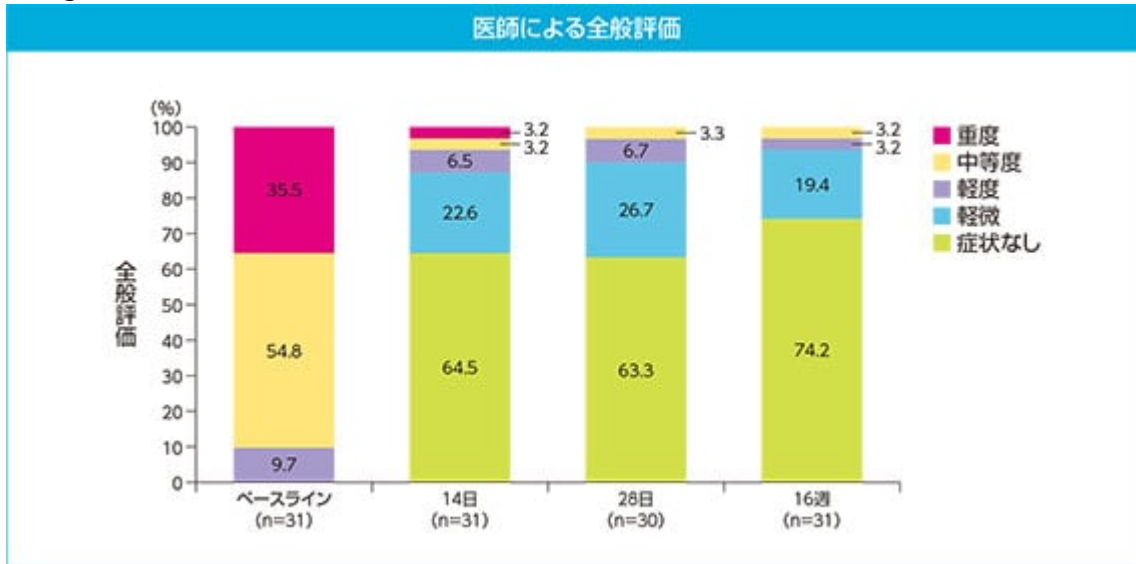
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□TRAPS □HIDS □crFMF □□□□□

医師による全般評価

ベースライン150mg 3 9.7 17 54.8 11 35.5
 14日 14 87.1 20 7 16 93.5

Image



5

SAF

crFMF N2301 16, SAF

Image

| | 再燃なし | | 再燃あり | | | イラリスを投与した患者 N=58 n(%) |
|--------------|---------------------------|---------------------|---|------------------------------------|---|-----------------------------|
| | 150mg q4w N=21 n(%) | プラセボ N=5 n(%) | 150mg q4w →300mg q4w N=10 n(%) | プラセボ →150mg q4w N=22 n(%) | プラセボ →150mg q4w →300mg q4w N=5 n(%) | |
| 有害事象 | 16(76.2) | 4(80.0) | 9(90.0) | 17(77.3) | 5(100.0) | 47(81.0) |
| 副作用 | 7(33.3) | 1(20.0) | 1(10.0) | 9(40.9) | 2(40.0) | 19(32.8) |
| 死亡 | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) |
| 重篤な有害事象 | 2(9.5) | 1(20.0) | 0(0.0) | 3(13.6) | 0(0.0) | 5(8.6) |
| 投与中止に至った有害事象 | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) | 0(0.0) |

150mg 76.2 16/21 5 23.8 4 19.0
 2 9.5

80.0 4/5 FMF 2 40.0 1 4.8

150mg 300mg 90.0 9/10 FMF 2 20.0 10.0

150mg 77.3 17/22 FMF 8 36.4 3 13.6 2 9.1

150mg 300mg 100.0 5/5 3 60.0 2 40.0

81.0 47/58 FMF 13 22.4 8 13.8 7
12.1 6 10.3

150mg 1 150mg 1 1

2 / 3
3

colchicine resistant Familial Mediterranean Fever (crFMF)
150mg 4

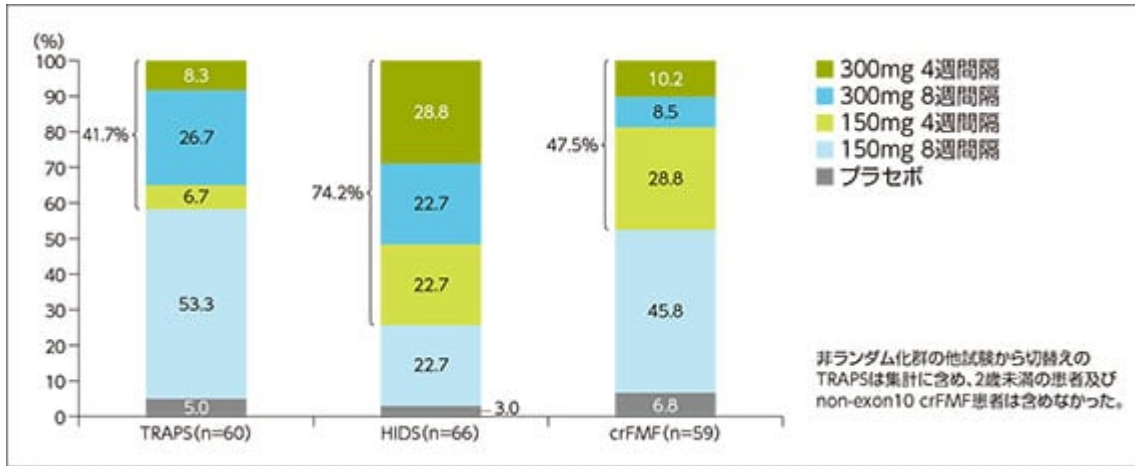
150mg index flare crFMF 19

150mg 4 index flare 1 1
150mg 8 150mg q8w

- 8 150mg 4
- 8 150mg 8
- 150mg 8 150mg 4

150mg 300mg
8 4

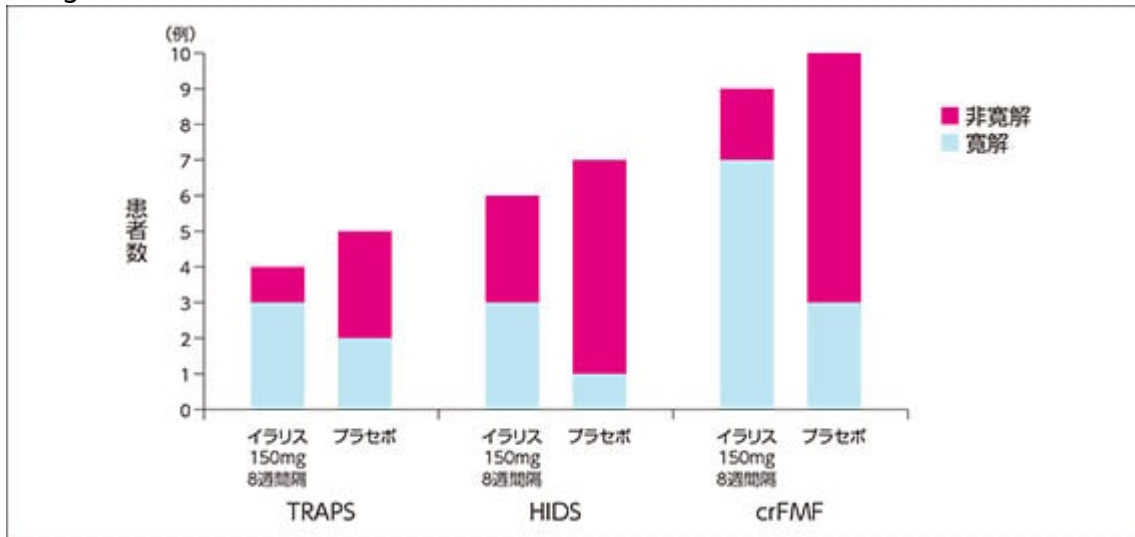
Image



2
3

-
- 150mg 8

Image



4

23.6% 13/55 9.1% 5 3.6% 2
3
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Source URL: https://prod.pro.novartis.com/jp-ja/products/ilaris/fmf/clinical_01