

!" #&/
4;O <548G=>3> 70AB>AC20==O ;V:0@AL:>3> 70A>1C

\$#"®
(PIMAFUCORT®)

!,:04:

4VNGV @5G>28=8: =0B0:>@B87>=, =5>
1 3 <07V : =0B0 3V4@>:>@B87>=C 10 <3, =5> 3,5 <3;
4>?>28=0: >;5>35;L ?>;V5B8;5=>289.

V:0@AL:0 D>@<0. 07L.

A=>2=V DV78:>-EVABV: <07L 2V4 1V;>3> 4> A2VB;>-6>2B>3> :>;L>@C.

\$0@<0:>B5@0?52B8G=0 3@C?0. >@B8:>AB5@>W48 4;O 70AB>AC20==O C 45@<0B>;>3VW.
>@B8:>AB5@>W48 C :><1V=0FVW 7 0=B81V>B8:0<8. >4 "% D07! 01.

\$0@<0:>;>3VG=V 2;0AB82>ABV.

\$0@<0:>48=0

V<0DC:>@B® :><1V=>20=89 ?@5?0@0B, I> 28=8: 3V4@>:>@B87>=, =5>
V4@>:>@B87>= :>@B8:>AB5@>W4, I> <0T ?@>B870?0;L=C B0 AC48=>72C6C20;L=C 4VN; 7<5=HCT
A25@1V6, O:89 AC?@>2>46CT @V7=V 2848 45@<0B>7V2.
5>B8:>< H8@>:>3> A?5:B@0 4VW, 0:B82=89 I>4> 45O:8E 3@078B82=8E (AB0DV;>:>:V2, 5=B5@>:>:V2)
V 3@0<=530B82=8E (*Klebsiella spp.*, *Proteus spp.*, *Escherichia coli*) 10:B5@V9. *Pseudomonas aeruginosa*
ABV9:0 4> =5>in vitro.
0B0 ?>;VT=>28E 0=B81V>B8:V2 3@C?8 <0:@>;V4V2, <0T DC=3VF84=C 4VN ?> 2V4=>H5==N 4>
V=D5:FV9, A?@8G8=5=8E 3@810<8, 7>:@5<0 *Candida spp.* 52V4><>, G8 ABV9:V 4> =0B0
5@5E@5A=0 @578AB5=B=VABL< B0 V=H8<8 0=B81V>B8:0<8 3@C?8 03;V:>784V2 <>65 28=8:0B8
G5@57 =0ABC?>V ?@8G8=8: @>728B>: ?;073;V:>7848 B0 7=86CNBL ?@>=8:=VABL ;VB8==>W<5
<1@0=8, C @57C;LB0BV G>3> 5D5:B 03;V:>784V2 7=86CTBLAO G5@57 ?>@CH5==O 5=5@35B8G=>3>
>1 @81>A><0;L=>W G0 >AB0==V9 <5E0=V7< 28=8:0T @V4:>.

\$0@<0:>:V=5B8:0.

1A>@1FVO

0B0 =5 01A>@1CNBLAO G5@57 =5CH:>465=C H:V@C B0 A;87>2V >1>;>=:8. >6;820 =57=0G=0
01A>@1FVO =5>465=C H:V@C, @0=8 B0 28@07:8. '5@57 =5CH:>465=C H:V@C 01A>@1CTBLAO
?@81;87=> 1-3 % 3V4@>:>@B87>=C; ?@8 5:75:>@B87>=C, I> 01A>@1CTBLAO, 71V;LHCTBLAO
242VGV, ?@8 V=D5:FV9=8E C@065==OE H:V@8 C 5 @07V2. # 4VB59 ABC?V=L 01A>@1FVW 7
<5=HCTBLAO 7 2V:>

;V=VG=V E0@0:B5@8AB8:8.

>:070==O. >@>B:>G0A=5 ;V:C20==O ?>25@E=528E 45@<0B>7V2, I> ?V440NBLAO
>@B8:>AB5@>W4=V9 B5@0?VW, CA:;04=5=V 2B>@8==>N 10:B5@V0;L=>N B0/01> 3@81:>2>N
V=D5:FVTN (>A>1;82> A?@8G8=5=5 3@810<8 @>4C *Candida*) GCB;828<8 4> =5>

@>B8?>:070==O.

A:V;L:8 V<0DC:>@B® :>@B87>= (:>@B8:>AB5@>W4 A;01:>W 4VW), VA=CNBL =0ABC?>V
?@>B8?>:070==O:

- 70E2>@N20==O H:V@8, A?@8G8=5=5 ?5@28==8<8 10:B5@V0;L=8<8 V=D5:FVO<8; ?5@28==8
<8 V=D5:FVO<8, A?@8G8=5=5 3@81:0<8 B0 4@V6460<8; ?0@078B0@=8<8 V=D5:FVO<8
(2;;NG0NG8 7=0G=V B0 BO6:V ?>H:>465==O H:V@8);
- 2V@CA=V V=D5:FVW;
- H:V@=V @0=8 B0 28@07:8, B@>DVG=V 28@07:8, >?V:8;
- ?>1VG=V @50:FVW, A?@8G8=5=5 :>@B8:>AB5@>W40<8 (?5@V>@0;L=89 45@<0B8B,
AB@8W);
- VEBV>7, N25=V;L=89 ?V4>H>2=89 45@<0B>7, 2C3@8 728G09=V (*acne vulgaris*), @>70F50, ;0
2>=>A=8E AC48= H:V@8, 0B@>DVO H:V@8.

V<0DC:>@B® =5 A;V4 70AB>A>2C20B8 C 7>2=VH=V9 A;CE>289 :0=0; ?@8 ?5@D>@0FVW
10@010==>W ?5@5B8=:8.
:@V< B>3>, V<0DC:>@B® =5 A;V4 70AB>A>2C20B8 C @07V 3V?5@GCB;82>ABV 4> =5> 03;V:>784V2
01> :>@B8:>AB5@>W4V2 (I> B@0?;OTBLAO 4C65 @V4:>), G8 4> 1C4L-O:8E 4>?>28=.

70T<>4VO 7 V=H8<8 ;V:0@AL:8<8 70A>10<8 B0 V=HV 2848 270T<>4V9. 0=V ?@> ;V:0@AL:C 270T
<>4VN V<0DC:>@BC® 2V4ACB=V.

A>1;82>ABV 70AB>AC20==O.

878: 28=8:=5==O 1VG=8E @50:FV9 7@>AB0T ?@8 71V;LH5==V B@820;>ABV ;V:C20==O.
8:>@8AB0==O >;N7V9=>W ?>2O7:8 (F5;>D0=>2>W) 01> 70AB>AC20==O C 4V;O=FV H:V@=8E A:;04:>
71V;LHCT B0:89 @878:.
(:V@0 >1;8GGO, 2>;>A8AB>W 4V;O=:8 H:V@8 3>;>28 B0 35=VB0;V9 T >A>1;82> GCB;82>N 4>
28=8:=5==O

0AB>AC20==O ?@5?0@0BC 2 4V;O=FV >1;8GGO, 738=0GV2 B0 V=H8E 4V;O=:0E B>=:>W H:V@8<>65
?@8725AB8 4> 0B@>DVW H:V@8 B0 ?V428I5==O 2A<:BC20==O ?@5?0@0BC.
>@B8:>AB5@>W48 4;O 3> 70AB>AC20==O <>6CBL 1CB8 =5157?5G=8<8 C ?0FVT=BV2 7 ?A>@V07<<
2=0A;V4>: @04C ?@8G8=, 2;;NG0NG8 «A8=4@< @8:>H5BC» 2=0A;V4>: @>728B:C B>;5@0=B=>ABV,
@878:C 28=8:=5==O 35=5@0;V7>20=>3> ?CABC;O@=>3> ?A>@V07C G8 W A8AB5<=>W
B>:A8G=>ABV 2=0A;V4>: ?>H:>465=>W 10@T@=>W DC=:FVW H:V@8. !B5@>W48 <>6=0
70AB>A>2C20B8 ?@8 ?A>@V07V H:V@8 3>;>28 G8 E@=>VG=>@V07V @C: B0 AB>?. 06;82>
@5B5;L=> A?>AB5@V30B8 70 E2>@8<8.

@8 =52V4?>2V4=>AC20==V 10:B5@V0;L=V, ?0@078B0@=V, 3@81:>2V B0 2V@CA=V V=D5:FVW
<>6CBL <0A:C20B8AO B0/01> 703>AB@N20B8AO.

5 A;V4 =0=>A8B8 ?@5?0@0B =0 ?>2V:8 G5@57 <>6;82VABL ?>B@0?;O==O =0 :>=N=:B82C V
?V428I5=89 @878: @>728B:C 3;0C:<<8 01> AC1:0?AC;O@=>W :0B0@0:B8.

@8 =0=5A5==V V<0DC:>@BC® =0 25;8:V 4V;O=:8 H:V@8, ?@8 70AB>AC20==V 4VBO< 01> 7
28:>@8AB0==O <>;N7V9=>W ?>2O7:8 (B>1B> C 28?04:0E, 2 O:8E 4>A2V4 70AB>AC20==O >1<565=89)
=5>1EV4=> 1@0B8 4> C2038 <>6;82VABL 28=8:=5==O 04@5=>:>@B8:0;L=>W AC?@5AVW.

A=CT <>6;82VABL O: ?5@5E@5A=>W A5=A81V;V70FVW< B0 B0:8<8 EV A?>@V4=5=8<8
0=B81V>B8:0<8 O: :0=0W @578AB5=B=>ABV < B0 V=H8<8 03;V:>7840<8.

V4?>2V4=>, 4;O ?V4B@8<0==O =5>1EV4=8E @V2=V2 03;V:>784V2 ?@8 WE A8AB5<=>AC20==V
=5>1EV4=> O:<<30 GVB:VH5 4>B@8:070=L I>4> 70AB>AC20==O B0 B@820;>ABV ;V:C20==O.

!;V4 C=8:0B8 4>23>B@820;>3> ;V:C20==O B0 =0=5A5==O =0 @0=8 01> ?>H:>465=C H:V@C G5@57
B5>@5B8G=89 @878: >B>B>:A8G=>ABV B0 =5D@>B>:A8G=>ABV 2=0A;V4>: 2A<:BC20==O =5>

0AB>AC20==O :><1V=0FVW :>@B8:>AB5@>W4V2, ?@>B83@81:>28E ?@5?0@0BV2 B0
0=B81V>B8:V2 ?>:070=5 ;8H5 70 28=OB:>28E >1AB028=. 5>1EV4=> ?>AB028B8 ?@028;L=89 4V03=>7 7
<5B>N 28:;NG5==O <>6;82>ABV @578AB5=B=>ABV >@30=V7:@5<8E 28?04:0E VA=CT

=5>1EV4=VABL C 70AB>AC20==V 42>E 01> 1V;LH5 4VNG8E @5G>28=. "8<=5 <5=H5, G0AB> 1060=89
@57C;LB0B <>6=0 4>AO3B8, 28:>@8AB>2CNG8 ?@5?0@0B, I> 4=C 4VNGC @5G>28=C.

28?04:C 28=8:=5==O AC?5@V=D5:FV9 G8 =043> @>ABC 3@81:>2>W V=D5:FVW ;V:C20==O
?@5?0@0B<< A;V4 ?@8?8=8B8 V ?@89=OB8 2V4?>2V4=V 70E>48.

!;V4 4>B@8A>1;82>W >15@56=>ABV 4;O ?0FVT=BV2 V7 =8@:>2>N =54>AB0B=VABN ?@8
70AB>AC20==V ;V:0@AL:8E 70A>1V2, I> 3;V:>7848.

0AB>AC20==O C ?5@V>4 203VB=>ABV 01> 3>4C20==O 3@C44N.

1<565=V 40=V I>4> 70AB>AC20==O =0B04 203VB=>ABV =5 28O28;8 ?V428I5=>3> @878:C 2@>465=8E
?>@CH5=L. @8 7>2=VH=L>AC20==V =0 =525;8:8E 4V;O=:0E A8AB5<=5 2A<:BC20==O =0B0

@8 A8AB5<=>AC20==V 03;V:>784V2 C ?5@V>4 203VB=>ABV 2V47=0G0;8AO 28?04:8

>B>B>:A8G=>ABV. @8 7>2=VH=L>AC20==V =0 =525;8:8E 4V;O=:0E A8AB5<=5 2A<:BC20==O 0
3;V:>784V2 3> B>:A8G=0 4VO =0 @5?@>4C:B82=C DC=:FVN.

>@B8:>AB5@>W48 740B=V ?@>=8:0B8 G5@57 ?;0F5=BC. 0 40=89 G0A C ;N459 =5 2V47=0G02AO
B5@0B>35==89 2?;82, I> 2V47=0G02AO C 4>A;V465==OE C B20@8=. @8 A8AB5<=>AC20==V

3;N:>:>@B8:>AB5@>W4V2 C 28A>:8E 4>70E 2V47=0G02AO 2?;82 =0 ?;V4/=>2>=0@>465=>3> (70B@8
CB@>1=>3> @>728B:C, 04@5=>AC?@5AVO). %>G0 VA=CNBL >k565=V 40=V I>4> 7>2=VH=L>3>

70AB>AC20==O 3;N:>:@B8:>AB5@>W4V2 C ;N48=8 C ?5@V>4 203VB=>ABV, =5>1EV4=>
2@0E>2C20B8 WE=T W 0:B82=>ABV (B0 ;:0A), B0:V O: 3V4@>:@B87>=, <>6=0 70AB>A>2C20B8
:>@>B:8<8 :C@A0<8 =0 >1<565=8E 4V;O=:0E H:V@8. ?8A0=V 28I5 5D5:B8 =5 <>6=0 28;;NG8B8 ?@8
B@820;>AC20==V 01> =0=5A5==V =0 25;8:V ?>25@E=V ?>H:>465=>W H:V@8.
V<0DC:>@B <>6=0 70AB>A>2C20B8 C ?5@V>4 203VB=>ABV :>@>B:8<8 :C@A0<8 =0 =525;8:8E
4V;O=:0E H:V@8. "@820;5 70AB>AC20==O 01> =0=5A5==O =0 25;8:V 4V;O=:8 ?>H:>465=>W H:V@8
<>6;82V BV;L:8 C :@09=VE 28?04:0E.
>4C20==O 3@C44N.

V4ACB=O V=D>@<0FVO ?@> <>6;82C A5:@5FVN =0B0
V<0DC:>@B® <>6=0 70AB>A>2C20B8 C ?5@V>4 3>4C20==O 3@C44N :>@>B:8<8 :C@A0<8 =0
=525;8:8E 4V;O=:0E H:V@8. @8 B@820;>AC20==V 01> =0=5A5==V =0 25;8:V 4V;O=:8 ?>H:>465=>W
H:V@8 3>4C20==O 3@C44N =5 @5:><5=4CTBLAO.

40B=VABL ??:820B8 =0 H284:VABL @50:FVW ?@8 :5@C20==V 02B>B@0=A?>@B< 01> V=H8<8
<5E0=V7<0<8.

V4ACB=V 40=V I>4> 2?;82C ;V:0@AL:>3> 70A>1C V<0DC:>@B® =0 740B=VABL :5@C20B8
02B>B@0=A?>@B< 01> <5E0=V7<0<8, B0 28=8:=5==O B0:>3> 2?;82C =5 ?5@5410G0TBLAO.

!?!>AV1 70AB>AC20==O B0 4>78.

@5?0@0B =0=>A8B8 B>=:8< H0@< =0 C@065=V 4V;O=:8 H:V@8 2-4 @078 =0 4>1C. "@820;VABL
:C@AC ;V:C20==O 287=0G0T V=482V4C0;L=> ;V:0@ 70;56=> 2V4 E0@0:B5@C 70E2>@N20==O. C@A
;V:C20==O, O: ?@028;>, =5 <0T ?5@528IC20B8 14 4=V2.

V<0DC:>@B® C 40=V9 ;V:0@AL:V9 D>@=VG=8E 70E2>@N20=L H:V@8, ?@8 O:8E 28=8:0NBL
C@065==O, I> AC?@>2>46CNBLAO ACEVABN H:V@8, CB2>@5==O< ;0AB>28==O B0 B@VI8=.

VB8. @5?0@0B 70AB>A>2C20B8 4VBO< 2V:< 2V4 1 @>:C, ?V4 =03;04< ;V:0@O.

5@54>7C20==O. 0=8E I>4> 28?04:V2 ?5@54>7C20==O =5<0T. B5>@5B8G=0 <>6;82VABL
>B>B>:A8G=>W 4VW =5>2=VH=L>3> A;CE>2>3> ?@>E>4C ?@8 =002=>ABV ?5@D>@0FVW
10@010==>W ?5@5B8=:8 B0 ?@O<>W 4VW =5>. :@5<8E 28?04:0E ?@8 28?04:>2> 2W C?0:>2:8
;V:0@AL:>3> 70A>1C V<0DC:>@B® V<>2V@=0 ?5@5=>A8728B:C B>:A8G=8E 5D5:BV2.

>1VG=V @50:FVW.

V4:> (>0,01%, <0,1 %)

1>:C 5=4>:@8==>W A8AB5<8.

4@5=>:@B8:0;L=0 AC?@5AVO 2=0A;V4>:3> 70AB>AC20==O ?@5?0@0BV2, I> @B8:>AB5@>W48,
@V4:> A?>AB5@V30TBLAO C 4>@>A;8E, V =5 ?5@5410G0TBLAO, I> 2>=0 <>65 28=8:=CB8 2=0A;V4>:
70AB>AC20==O ;V:0@AL:>3> 70A>1C V<0DC:>@B®. >6;82VABL @>728B:C A8AB5<=8E 5D5:BV2
71V;LHCTBLAO ?@8 28:>@8AB0==V >;N7V9=>W ?>207:8, =0=5A5==V =0 25;8:V 4V;O=:8 H:V@8,
?@8 70AB>AC20==V ?@>BO3< B@820;>3> G0AC, 0 B0:>6 C 4VB59.

1>:C H:V@8 B0 ?V4H:V@=>W ;:VB:>28=8.

@8 70AB>AC20==V ;V:0@AL:>3> 70A>1C V<0DC:>@B® A?>G0B:C <>65 28=8:=CB8 =57=0G=5
703>AB@5==O 7 1>:C H:V@8. &5 =5 ?>B@51CT ?@8?8=5==O ;V:C20==O.

- @50:FVW 3V?5@GCB;82>ABV, ?5GV==O B0 ?>4@07=5==O H:V@8, 45@<0B8B, 5:75<0,
:=B0:B=89 45@<0B8B;
- :=B0:B=V 0;5@3VG=V @50:FVW, >A>1;82> =0 =5>
- <>6CBL 28=8:=CB8 =0ABC?=V ?>1VG=V 5D5:B8 :>@B8:>AB5@>W4V2, 0;5 WE
2V@>3V4=VABL ?@8 70AB>AC20==V 3V4@>:@B87>=C =86G0, =V6 B8E, I> 28=8:0NBL ?@8
70AB>AC20==V :>@B8:>AB5@>W4V2 1V;LH 28A>:>W 0:B82=>ABV:
 - 0B@>DVO H:V@8, G0AB> =5>1>@>B=0, I> AC?@>2>46CTBLAO ?>B>=H0==O< H:V@8,
B5;50=3V>5:B07VO<8, ?C@?C@>N B0 AB@8O<8;
 - @>70F50?>4V1=89 B0 ?5@V>@0;L=89 45@<0B8B, I> AC?@>2>46CTBLAO 01> =5
AC?@>2>46CTBLAO 0B@>DVTN H:V@8;
 - 5D5:B «@8:>H5BC», I> <>65 A?@8G8=8B8 AB5@>W4=C 70;56=VABL;
 - C?>2V;L=5=5 703>N20==O @0=;

- 45?V3<5=B0FVO, 3V?5@B@8E>7.

878: 28=8:=5==O 1VG=8E @50:FV9 7@>AB0T ?@8 71V;LH5==V B@820;>ABV ;V:C20==O.

8:>@8AB0==O >;N7V9=>W ?>2O7:8 (F5;>D0=>2>W) 01> 70AB>AC20==O C 4V;O=FV H:V@=8E A:;04>: 71V;LHCT B0:89 @878:.. (:V@0 >1;8GGO, 2>;>A8AB>W 4V;O=:8 H:V@8 3>;>28 B0 35=VB0;V9 T >A>1;82> GCB;82>N 4> 28=8:=5==O

@8 =52V4?>2V4=>AC20==V 10:B5@V0;L=V, ?0@078B0@=V, 3@81:>2V B0 2V@CA=V V=D5:FVW <>6CBL <0A:C20B8AO B0/01> 703>AB@N20B8AO.

C65 @V4:> (< 0,01 %)

1>:C >@30=V2 7>@C: ?V428I5==O 2=CB@VH=L>>G=>3> B8A:C, 71V;LH5==O @878:C @>728B:C :0B0@0:B8.

'0AB>B0 =52V4><0

1>:C H:V@8 B0 ?V4H:V@=>W ::VB:>28=8: H:V@=V 28A8?0==O, A25@1V6 ?CABC;L>7=5 0:=5.

878: A8AB5<=8E 5D5:BV2 ?V428ICTBLAO C =0ABC?=8E 28?04:0E: 70AB>AC20==V 7 28:>@8AB0==O< ?>2O7:8 (F5;>D0=>20 ?>2O7:0 01> C 4V;O=:0E H:V@=8E A:;04>:); 70AB>AC20==V =0 25;8:8E 4V;O=:0E H:V@8; 4>23>B@820;>AC20==V 4VBO< (4VB8 =04728G09=> GCB;82V G5@57 =0O2=VABL C 4VB59 B>=:>W H:V@8 B0 2V4=>A=> 25;8:>W ?;>IV WW ?>25@E=V); =0O2=VABL :>5=BV2 01> 4>?>28=, I> ?>A8;NNBL ?@=>8:=5==O G5@57 @>3>289 H0@ B0/01> ?>A8;NNBL 5D5:B 4VNG>W @5G>28=8.

878: @>728B:C 1VG=8E @50:FV9 71V;LHCTBLAO 7V 7@>AB0==O< A8;8 4VW ?@5?0@0BC B0 B@820;>ABV ;V:C20==O. 0AB>AC20==O V7 28:>@8AB0==O< ?>2O7:8 (F5;>D0=>20 ?>2O7:0 01> =0=5A5==O C 4V;O=:0E H:V@=8E A:;04>:?) ?V428ICT F59 @878:.. (:V@0 >1;8GGO B0 2>;>A8AB>W 4V;O=:8 3>;>28, 0 B0:>6 35=VB0;V9, >A>1;82> GCB;820 I>4> 28=8:=5==O ?>1VG=8E @50:FV9. @8 =52V4?>2V4=>AC20==V, 0 B0:>6 ?@8 =0O2=>ABV 10:B5@V0;L=8E, ?0@078B0@=8E, 3@81:>28E 01> 2V@CA=8E V=D5:FV9 ?@>O28 F8E 70E2>@N20=L <>6CBL <0A:C20B8AO B0/01> ?>A8;N20B8AO.

"5@ABV. 5 @>:V2.

#<>28 715@V30==O. □15@V30B8 ?@8 B5

15@V30B8 C =54>ABC?=>

#?0:>2:0.> 15 3 <07V 2 BC1V; ?> 1 BC1V 2 :0@B>==V9 :>@>1FV.

0B53>@VO 2V4?CA:C. 0 @5F5?B>

8@>1=8:.. "5<<;5@ B0;V0 !.@.:., B0;VO.

VAF57=0E>465==O 28@>1=8:0 B0 9>3> 04@5A0 20465==O 4VO;L=>ABV. "5<<;5@ B0;V0 !.@.:.: V0 45;;5 =40AB@V, 2, 20061, 0@C30B5 (), B0;VO/TemmlerItalia S.r.l.: Via delle Industrie 2, 20061 Carugate (MI), Italy.

0O2=8:.. AB5;;0A \$0@<0 .@>? ../Astellas Pharma Europe B. V.

VAF57=0E>465==O 70O2=8:0.

!8;L2VCA253, 62, 2333 BE 5945=, V45@;0=48/Sylviusweg, 62, 2333 BE Leiden, the Netherlands.

@54AB02=8FB2> 2 #: @0W=V: 04050, <. 8W2, 2C;. 8<>=5=:0, 13, :>@?. 7-, >DVA 41.

28?04:C 28=8:=5==O ?>1VG=8E 5D5:BV2 ?@>A8<> =0?@02;OB8 V=D>@<0FVN 4> ?@54AB02=8FB20 AB5;;0A \$0@<0 .@>? .. =0 04@5AC: 04050,